

EXHIBIT M

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK: PART 48

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IN RE: OPIOID LITIGATION

INDEX NO.: 400000/2017

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September 10, 2020
Central Islip, New York

MINUTES OF FRYE HEARING
(Testimony of Dr. Keyes)

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Supreme Court Justice

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OFFICIAL COURT REPORTER

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THE CLERK: Supreme Court, Suffolk
County, Part 48 is now in session, the
Honorable Jerry Garguilo presiding.

THE COURT: Good morning.

THE CLERK: Good morning, your Honor.

THE COURT: Good morning.

CHORUS. Good morning, your Honor.

THE COURT: I understand we're having a
little bit of an issue this morning.

THE CLERK: On the Hearing Calendar, In
Re Opioid Litigation, Index Number 400000 of
'17. Your appearances, please.

MR. REISMAN: Michael Reisman from the
New York Attorney General's Office for
Plaintiff, State of New York.

THE COURT: Good morning, Mr. Reisman.

MR. REISMAN: Good morning, sir.

MR. BADALA: Good morning, your Honor.
Salvatore Badala for Plaintiff Nassau County.

THE COURT: Good morning.

MS. CONROY: Jayne Conroy for the
Plaintiff Suffolk County.

THE COURT: Good morning.

MR. SHERIDAN: Tom Sheridan, Suffolk

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County.

THE COURT: This is someone from Suffolk County?

MR. SHERIDAN: Tom Sheridan for Suffolk County.

THE COURT: Good morning.

MS. DO AMARAL: Good morning, your Honor. Paulina do Amaral for Plaintiff.

MR. SCHMIDT: Good morning, your Honor. Paul Schmidt for McKesson.

THE COURT: Good morning.

MR. HALPERIN: Good morning, your Honor. Greg Halperin for McKesson.

THE COURT: Good morning.

MR. ERCOLE: Good morning, your Honor. This is Brian Ercole from Morgan Lewis on behalf of the Teva Defendants. I'll be questioning this remotely.

THE COURT: Okay. Before we start, like I've been doing every day, I'll just read into the record the rules of the Chief Judge. Keep in mind that whether you're observing these proceedings by live stream, the location you're at and observing and

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1
2 listening is deemed the court under Section
3 29.1: General, taking photographs, films or
4 videotapes, or audio taping, broadcasting or
5 telecasting in a courthouse, including any
6 courtroom, office, or hallway thereof, at any
7 time or on any occasion, whether or not the
8 court is in session, is forbidden, unless
9 permission of the Chief Administrator of the
10 courts or a designee of the Chief
11 Administrator is obtained.

12 Thank you. You will all be guided
13 accordingly. I understand we have a witness
14 in person today.

15 MR. REISMAN: That's correct, your
16 Honor.

17 THE COURT: Okay. You may call the
18 witness.

19 MR. REISMAN: Your Honor, Plaintiffs
20 call Dr. Katherine Keyes.

21 THE COURT: Dr. Keyes, good morning.

22 THE WITNESS: Good morning.

23 THE COURT OFFICER: Stand right here and
24 raise your right hand and face the Clerk.

25 (WHEREUPON, the Dr. Katherine Keyes,

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having first been duly sworn by the Clerk of
the Court, testified as follows:)

THE CLERK: Please state your name and
address for the record.

THE WITNESS: My name is Katherine
Keyes. My address is 236 Sackett Street,
Brooklyn, New York.

THE CLERK: You may be seated.

THE COURT: Good morning, Dr. Keyes.

THE WITNESS: Good morning.

THE COURT: Doctor, I'm Judge Garguilo.
I'm presiding over this case. I give all
witnesses the same three pointers. Of course
you know you're going to be asked a lot of
questions today, right?

THE WITNESS: Yes.

THE COURT: Pointer Number 1, listen
carefully to the question as put to you and
as best you can, limit your answer to the
information sought by the question.

For instance, if I were in that seat and
I was asked on which street do I live, I
would simply offer the name of the street. I
would not volunteer the town, the state, the

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county, or the ZIP code.

Rule Number 2, although it's not impolite in life to commence an answer before a question is complete, we save time that way in our day-to-day conversations; however, I'm sure you understand that we require a complete stenographic record.

So even though you know exactly where a question is going, wait for it to be complete before you commence your answer. And, lastly, if you hear the word objection or anything that sounds like objection, just stop until I give you direction, okay?

THE WITNESS: Okay.

THE COURT: You may proceed,
Mr. Reisman.

MR. REISMAN: Thank you, your Honor.

DIRECT EXAMINATION

BY MR. REISMAN:

Q. Dr. Keyes, we'll get into your background and methodology in more detail, but I'd like to ask you some preliminary questions. Where do you live?

A Brooklyn, New York.

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THE COURT: Sackett Street.

THE WITNESS: Sackett Street.

BY MR. REISMAN:

Q. For how long have you lived in New York State?

A About 20 years.

Q. What is your profession?

A I'm an epidemiologist.

Q. Can you tell the Court what epidemiologists do?

A Epidemiology is the science of what causes health outcomes so that we can identify populations that are at risk.

Q. Do epidemiologists ever draw causal inferences?

A Yes.

Q. What methodology do epidemiologies use to do that?

A We conduct studies, and do data analysis, and review literature.

Q. Is there anything novel about that methodology?

A No.

Q. Is there a consensus in epidemiology

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1 that a body of scientific literature can be relied
2 upon to support a causal inference?
3

4 A Yes.

5 Q. Can you give an example in epidemiology
6 where that's the case where a body of literature has
7 been relied on on which there's consensus that the
8 literature supports a causal inference?

9 A You know, I think the most classic
10 example is smoking and lung cancer. You know, there
11 were many studies conducted of cigarette smoking,
12 and we've come to a consensus that smoking is a
13 cause of lung cancer.

14 Q. So epidemiologists have relied on
15 studies. What kinds of studies have epidemiologists
16 relied onto draw the causal inference about smoking
17 and lung cancer?

18 A What we call observational studies.

19 Q. And observational studies are generally
20 accepted as a reliable methodology in your field of
21 epidemiology?

22 A Yes.

23 Q. With respect to the link between smoking
24 and lung cancer, would it be ethical to try to prove
25 that smoking causes lung cancer by doing a

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1
2 randomized controlled trial to see how many smokers
3 get lung cancer?

4 A No.

5 Q. Why not?

6 A Because we know that smoking is a health
7 hazard.

8 Q. In this case, do you plan to offer
9 certain opinions about whether there's a causal
10 relationship between exposure to prescription
11 opioids on the one hand and on the other hand
12 certain harms such as opioid use disorder, opioid
13 overdose death and so on?

14 A Yes.

15 Q. In your opinion, is there a causal
16 relationship between exposure to prescription
17 opioids and harms?

18 A Yes.

19 Q. In this case do you plan to offer
20 certain opinions about whether there's a causal
21 relationship between the increased supply of opioids
22 in New York and Nassau and Suffolk Counties since
23 the 1990s on the one hand and on the other hand
24 harms?

25 A Yes.

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1
2 Q. In your opinion, is there a causal
3 relationship between those two things?

4 A Yes.

5 MR. REISMAN: Now, I'd like to ask you
6 some questions about your qualifications to
7 offer opinions in this case. And with the
8 Court's permission, we'll show some slides
9 for demonstrative purposes.

10 THE COURT: Sure.

11 BY MR. REISMAN:

12 Q. Dr. Keyes, what is your academic
13 position?

14 A I'm an associate professor of
15 epidemiology at Columbia University School of Public
16 Health.

17 Q. What is your specialty as an
18 epidemiologist at Columbia?

19 A I predominantly study substance abuse
20 disorders and other psychiatric disorders.

21 Q. Can you tell the Court what degrees you
22 have?

23 A I have an MPH in epidemiology, which is
24 a Master's degree in public health, and then I have
25 a Ph.D. in epidemiology as well.

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2 Q. Did you do any academic work after
3 receiving your Ph.D.?

4 A I did a post doctoral fellowship in the
5 Department of Epidemiology at Columbia University
6 before joining the faculty.

7 Q. Do you have tenure at Columbia?

8 A Yes.

9 Q. Since completing your fellowship, have
10 you been on the Columbia faculty the entire time?

11 A Yes.

12 Q. Can you give the Court a few examples of
13 courses that you teach at Columbia?

14 A I teach graduate level courses at
15 Columbia University. I teach our graduate course in
16 psychiatric epidemiology as well as other courses in
17 epidemiological methods and statistical methods for
18 public health.

19 Q. Do you serve on any committees at
20 Columbia?

21 A Yes.

22 Q. Can you give the Court an example of
23 one?

24 A I am on the committee that writes the
25 epidemiological methodology questions that qualify

1 students to get a Ph.D. in epidemiology.

2 Q. Do you have graduate students in
3 epidemiology whose work you supervise personally?
4

5 A Yes.

6 Q. And do you supervise those graduate
7 students at Columbia regarding epidemiological
8 methods?

9 A Yes.

10 Q. Now, in your field of epidemiology, you
11 have published textbooks and articles in scientific
12 journals; is that right?

13 A Yes.

14 Q. Can you give the Court a very general
15 idea of how much you have published in your field in
16 terms of textbooks and articles?

17 A Yes. I've published around 270
18 peer-reviewed journal articles and about 50
19 additional editorials and book chapters.

20 I've been the author of three books, two
21 that are epidemiological method textbooks, and I
22 coedited a volume on drawing causal inferences for
23 psychiatric disorders.

24 Q. With respect to the first category, the
25 270 peer-reviewed articles, can you explain to the

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Court what that means in your field of epidemiology where -- the work that you've done to be peer-reviewed?

A Yes. We submit articles to journals, and those journals will invite other experts in the field to evaluate the rigor of the work. And to the extent that experts, other experts decide that it is rigorous, sufficiently rigorous and novel, those articles would be published.

Q. So those 270 articles that you've published in peer-reviewed journals, your peers in the field have determined that your methodology in those studies is generally accepted in the field; is that right?

A Yes.

Q. Now, with respect to that group of articles, for how many were you the primary author of?

A About 70.

Q. How many of those articles, again, the larger set of 270, were published -- that you published focused on opioid use and related harms?

A About 20.

Q. Can you tell the Judge about some of the

journals in which your research has appeared?

A Yes. I published in predominantly epidemiology journals, that is the American Journal of Epidemiology, the International Journal of Epidemiology, as well as the JAMA journals, the pediatrics, and then substance abuse journals like addiction and drug and alcohol dependence.

Q. Do you measure in any way the impact of your work on other researchers in the field of epidemiology?

A Yes.

Q. Can you give an example of how that's measured, your impact?

A Yes. We evaluate how often our articles are cited by others which is indicative of their impact.

Q. Do you have any examples of numbers of how many times your articles have been cited by other epidemiologists?

A Yes. About 50 of my articles have been cited more than 100 times which is indicative of impact.

Q. Now, let's talk about your textbooks. On the screen now is -- on the right-hand side of

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the slide, that's the cover of one of your textbooks; is that right?

A Yes.

Q. And the title is Epidemiology Matters a New Introduction to Methodological Foundations; is that right?

A That's right.

Q. That was published by Oxford University Press in 2014?

A Yes.

Q. Can you briefly tell the Court how you came to be the co-author of a textbook on epidemiological methodology?

A I had been teaching graduate students epidemiological methods and used -- developed my own materials for teaching my course, and those were popular materials.

And so the department chair, at the time Sandro Galea, who was the chair of the department of epidemiology, suggested that he and I form it into a textbook.

Q. Where is that textbook used?

A In graduate schools in public health.

Q. Do you know approximately in how many

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graduate schools your textbook is used?

A I estimate about 20.

Q. Are you an editor for any scientific journals?

A Yes.

Q. Which ones?

A I'm an Associate Editor For Drug and Alcohol Dependence. I'm also a Field Editor for alcoholism: Clinical and Experimental Research.

Q. Are you on the boards of any professional associations?

A Yes.

Q. Which ones?

A I'm on the executive committee of the Society For Epidemiological Research.

Q. What is that society?

A That is one of the oldest organizations, professional organizations for epidemiologists interested in methods.

Q. How did you come to serve on that board?

A I was elected by my peers.

Q. Can you tell the Court about a national award that you received?

A Yes. Several years ago I received the

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Early Stage Investigator award from the Office of Disease Prevention from the National Institute of Health.

Q. And the National Institutes of Health, that's sometimes abbreviated as NIH; is that right?

A That's right.

Q. And that's a federal government organization?

A Yes.

Q. And with respect to the award that you received in 2017 from the NIH, how many researchers around the United States receive that award each year?

A Two.

Q. So you were one of the two in 2017; is that right?

A Yes.

Q. I just want to go back briefly to your articles, the 270 articles that you published in peer-reviewed journals. I want to ask you this. When were you first engaged as an expert in opioid litigation?

A I don't -- I think about 2018.

Q. Okay. So since 2018 have you disclosed

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2 to journals to which you have submitted your work,
3 have you disclosed your role as an expert witness in
4 opioid litigation?

5 A Yes.

6 Q. Have you disclosed your role to each and
7 every journal that you have submitted your work to?

8 A When it's relevant to the article, yes.

9 Q. Do the journals always publish the
10 disclosures that you submit?

11 A No.

12 Q. So sometimes journals make errors in
13 printing your disclosures; is that right?

14 A That's right.

15 Q. What, if anything, have you done to
16 correct omissions or errors in disclosures that
17 journals have made regarding your disclosures?

18 A I've contacted the journal.

19 Q. Can you give an example of a situation
20 in which you have contacted a journal asking them to
21 correct your disclosures in a printed article that
22 you've authored?

23 A Yes. Last year there was an article
24 that I was a co-author on about stigma as a driver
25 of opioid use disorder, and there was not a

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disclosure printed in the journal. So I contacted the journal and asked them to change it.

Q. So, just to be clear, was it the case that the journal did not, in fact, print the disclosure information you had submitted to them?

A Yes.

Q. And had you disclosed to that journal that you have been serving as an expert in opioid litigation?

A Yes.

Q. So did you ask them to correct that disclosure so that the article would contain that information about your work on opioid litigation?

A Yes.

MR. REISMAN: Now, I'd like to look at an example of one of your published articles in the opioids area, and with the Court's permission, we're going to, in conjunction with the slide, we'll be doing this throughout this morning, we'll hand out a demonstrative exhibit which is the actual article that is represented by the slide.

THE COURT: Thank you.

MR. REISMAN: And that is Demo 56.

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MR. SCHMIDT: Can we get the actual slides? We can't get a hardcopy.

MR. REISMAN: They should be sent to you.

MR. BADALA: I emailed them. We're printing a hardcopy right now. I sent the electronic version.

MR. SCHMIDT: Thank you.

THE COURT: Somebody is going to be presented that.

MR. REISMAN: Yes. So we'll have a copy for the Court, for the witness, and for Defendants sitting at the table.

And these, as we present the documents, they'll also be made available electronically.

THE COURT: Thank you.

BY MR. REISMAN:

Q. Dr. Keyes, the slide shows a study that you published back in 2015; is that right?

A Yes.

Q. And the title of this study is, Prescription Opioids in Adolescence and Future Opioid Misuse; is that right?

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A That's right.

Q. And it was published in a peer-reviewed journal, Pediatrics?

A Yes.

Q. And that was three years, approximately, before you became involved as an expert witness in opioids litigation; is that right?

A Correct.

Q. What was your role in this particular study?

A I was involved in forming the data analysis, interpreting the results, and writing the paper.

Q. Can you briefly explain to the Court the methodology that you and your coauthors employed in that study?

A Yes. These data were drawn from a study called Monitoring the Future, and we used -- the subjects were repeatedly interviewed over time, and we used a longitudinal data analysis to determine whether prior exposure to prescription opioids were associated with future misuse of opioids.

Q. So you said a couple of things that I want to unpack.

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First, you mentioned the Monitoring the Future study. Can you briefly explain what that is? That's something separate from this study that you published in 2015; is that right?

A It's a bigger study than -- this is one paper from the larger study.

Q. Would it be fair to say that Monitoring the Future is a questionnaire?

A It is methodology that includes a questionnaire.

Q. So -- and you said it's given to high school students over time; is that right?

A It's -- yes, one component -- the baseline survey is given to high school students, and then there is a longitudinal follow-up of those high school students over time as well after they leave high school.

Q. And what do you mean by longitudinal?

A I mean that the same respondents are measured multiple times over development.

THE COURT: Doctor, excuse me. Is there a term of art in this methodology?

THE WITNESS: Longitudinal study or cohort study might be more appropriate.

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THE COURT: Thank you.

BY MR. REISMAN:

Q. When did the Monitoring the Future study begin?

A 1976.

Q. Do you personally have any role in the Monitoring the Future study?

A Yes.

Q. What is your role?

A I'm a coinvestigator of the grant that is funded to conduct the study, and I also have my own independent NIH funding to do analyses of the Monitoring the Future data.

Q. Have you yourself done analysis of the Monitoring the Future survey data?

A Yes.

Q. Is it fair to say that you have extensive knowledge of the Monitoring the Future survey?

A Yes.

Q. In your work on this case, have you relied on that knowledge in analyzing studies that use data from this survey?

A Yes.

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Q. What were the findings of this study?

A We found that opioid use prior to 12th grade that was prescribed by a doctor was associated with an increased risk of future opioid misuse.

Q. So you mentioned opioid use prescribed by a doctor. Is that sometimes referred to as medical use of opioids?

A Yes.

Q. So, in other words, did the study ask high school students whether a doctor -- whether they had taken opioids because a doctor told them to?

A Yes, that's right.

Q. And then the study followed up the opioid use of those individuals; is that right?

A That's correct.

Q. Is -- so did the study look to see whether those individuals who had taken opioids that a doctor told them to take later on misused opioids?

A That's right.

Q. Now, opioid misuse and opioid use, is there any overlap between those two concepts?

A Yes. They are correlated.

Q. When you say they're correlated, what do

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you mean?

A I mean that individuals who use opioids medically are more likely to use opioids nonmedically than individuals who don't, and visa-versa.

Individuals who use opioids nonmedically are more likely to use opioids medically.

Q. So sometimes individuals can go back and forth between medical use and nonmedical use of opioids; is that fair?

A That's fair.

Q. Now, this slide that we're showing right now, does that represent the concept that you just described?

A Yes.

Q. Would you say that medical and nonmedical use of prescription opioids are intertwined?

A Yes.

Q. Let's -- we'll back up just a moment and just a few more questions on this 2015 study that you coauthored.

You mentioned your findings with respect to the link between medical use of opioids and

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1 nonmedical use. Can you please explain to the Court
2 why in that study, the finding that you and your
3 colleagues reached was provided?
4

5 A Yes. With addition to the cohort
6 design, we also controlled for many variables that
7 we consider to be what are called confounding
8 factors.

9 Q. What do you mean by confounding factors?

10 A These are factors that would be
11 associated with both the exposure, which is in this
12 case prescription opioid use, and the outcome,
13 future opioid misuse.

14 Q. Can you give an example of a confounding
15 factor that you and your colleagues accounted for in
16 this study?

17 A Yes. We accounted for prior substance
18 misuse. So, you know, the prior -- the misuse of
19 other drugs before opioid misuse.

20 Q. Is it fair to say that you and your
21 colleagues accounted for that other factor in order
22 to be able to determine whether it was, in fact, a
23 medical use of opioids that was causing or linked to
24 the nonmedical use of opioids?

25 A That's the intention, yes.

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Q. And that's what you did in that study?

A Yes.

Q. And that is a generally accepted methodology in your field of epidemiology; is that right?

A That's right.

Q. Are you involved today in any research involving opioids?

A Yes.

Q. Can you tell the Court about some of the research that you are involved in today?

A One project is the Helping End Addiction Long-Term project or HEALing Communities Study.

Q. What is that?

A So that is an NIH-funded organization science project that is taking place across four states including New York with the goal of reducing opioid overdose by 40 percent.

Q. So the HEALing Communities study, that's a federally funded study that involves New York and a few other states; is that right?

A That's right.

Q. And in New York State there are 16 counties involved. That's what we see on the slide

here; is that right?

A That's right.

Q. And is Suffolk County one of those counties?

A Yes.

Q. And there are counties all across the state. Is that because opioids have impacted communities across New York State?

A Yes.

Q. You mentioned that the study is aiming to reduce opioid overdose by 40 percent. How is it trying to do that?

A The study is working with communities to identify community-led initiatives that would reduce opioid overdose focusing on increased access to medication for opioid use disorder, increased access to tertiary prevention techniques such as the naloxone access as well as reducing opioid prescribing.

Q. How were you chosen to become an investigator on the HEALing Communities study?

A I have over a decade of expertise in mathematical modeling which is an important component of the HEALing Communities study.

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2 Q. So your role in the study involves
3 mathematical modeling regarding the goals of the
4 project?

5 A That's right.

6 Q. How are you developing those
7 mathematical models? Are you looking to any sort of
8 literature?

9 A Yes.

10 Q. What literature are you looking at to
11 develop your mathematical models?

12 A We synthesize the existing literature on
13 the parameters that are important for modeling
14 opioid use, opioid use disorder, and the transition
15 to overdose. So synthesizing available literature
16 as well as available data to inform those
17 parameters.

18 Q. So the methodology that you just
19 described, reviewing and synthesizing scientific
20 literature, is that a generally accepted methodology
21 in your field?

22 A Yes.

23 Q. Is there a consensus in your field that
24 that is how research is done and how researchers can
25 form conclusions?

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A Yes.

Q. And that methodology, the review and synthesis of scientific literature, is that the methodology that you employed in this case?

A Yes.

Q. Dr. Keyes, are your opinions in this case based on your education, training, and experience as an epidemiologist?

A Yes.

Q. And have you brought to bear in your work in this case, your knowledge of the conditions surrounding opioid use and misuse in the State of New York and in Nassau and Suffolk Counties?

A Yes.

Q. I'd like to move on now to talking about your assignment and delving deeper into your methodology.

Does this slide summarize in general terms your assignment in this case related to causation?

A Yes.

Q. So the first point is that you described the harms associated with opioid use in New York State and in Nassau and Suffolk Counties; is that

right?

A That's right.

Q. And then you assessed the causes of those harms, correct?

A That's right.

Q. Now, this next slide, does this summarize your methodology that you applied in this case?

A Yes.

Q. We're going to mark as an exhibit, a demonstrative exhibit your expert report in this case. It's P-23954.

So your methodology in this case, as shown in this slide, is to assess whether there is an association between exposure to prescription opioids and opioid use disorder, opioid overdose and of the harms and whether those associations are causal; is that right?

A Yes.

Q. And to do that, you --

MR. ERCOLE: Your Honor, I apologize for interrupting the question. This is Brian Ercole. It's a little bit hard to hear the witness in certain instances.

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For instance, I couldn't hear the witness' last answer. I don't know if there's a way of asking her to speak closer into the microphone. I, again, apologize for interrupting.

THE COURT: Thank you. We made a little adjustment.

THE WITNESS: I'll try to keep more --

THE COURT: How is that? Is that better?

MR. ERCOLE: It is. I really appreciate that. Thank you.

THE COURT: You're welcome.

Go ahead.

BY MR. REISMAN:

Q. So, Dr. Keyes, the factors listed there are factors that you used in implementing your methodology in this case; is that right?

A Yes.

Q. And those factors are: Dose-response relationship, temporal relationship, strength of the association, replication, biological plausibility, and consideration of alternative explanations; is that right?

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A Yes.

Q. Where did you get that methodology?

A Those are standard factors in my field that we use when evaluating, synthesizing a body of literature.

Q. Do you use that methodology in your work as an epidemiologist on a daily basis?

A Yes.

Q. Is there anything novel about that methodology?

A No.

Q. Is that methodology generally accepted in your field?

A Yes.

Q. In your work on this case, did you use this methodology in the same way that you do in your work as an epidemiologist?

A Yes.

Q. So I'd like to take a few minutes to go through each of these factors to have you explain what they mean and explain how you applied them.

First we have dose-response relationship. Can you explain to the Court what that means?

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2 A Yes. We look to see whether there is a
3 greater risk of the outcome as the dose of the
4 exposure under investigation increases.

5 Q. So, for example, you looked to see
6 whether greater exposure to prescription opioids led
7 to certain outcomes such as opioid misuse, opioid
8 use disorder, opioid overdose and other harms; is
9 that right?

10 A That's right.

11 Q. And you discussed dose-response
12 relationship in your expert report in this case,
13 right?

14 A Yes.

15 Q. Now, to apply this factor of dose
16 response, how did you do that? What did you do?

17 A I looked for studies that evaluated
18 different risks of outcomes based on increasing dose
19 and duration of opioid use.

20 Q. Now, let's break that down. So when you
21 talk about increasing dose, is there a way that is
22 generally accepted in your field of measuring the
23 dose of a drug, in this case prescription opioids?

24 A Yes.

25 Q. Is that sometimes referred to as

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morphine milligram equivalents?

A Yes.

Q. Or MMEs?

A Yes.

Q. And what is that?

A That is a conversion factor. So if you have different opioid products that have different strengths and potencies, you can compare across different products on comparing apples to apples, let's say.

Q. And is that based on the relative strength of an opioid as compared to marketing?

A Yes.

Q. So if an opioid has an MME, if it's 50 MMEs, that means it's 50 times as strong as morphine; is that right?

A Yes.

Q. Now, you talked about duration. Does that essentially mean how many days a person is taking opioids?

A Yes.

MR. REISMAN: Let's look at a study that illustrates how you applied dose response. It's Demo 48.

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THE COURT: Doctor, while we're looking at this document, I have a question. You testified about this methodology.

THE WITNESS: Yes.

THE COURT: Is there a founding father of this methodology?

THE WITNESS: Bradford Hill is commonly cited as one of the epidemiologists who wrote on this topic.

THE COURT: Is he still with us?

THE WITNESS: I don't think so.

THE COURT: Okay. Thank you.

BY MR. REISMAN:

Q. So this slide shows a study by Edlund and colleagues published in the Clinic Journal of Pain in 2014; is that right?

A That's right.

Q. And you discussed this study in your report, right?

A Yes.

Q. Now, the conclusion that is shown here from the abstract is that among individuals with a new CNCP episode, prescription opioid exposure was a strong risk factor for incident OUDs. Did I read

1 that correctly?

2 A Yes.

3 Q. And CNCP stands for chronic non-cancer
4 pain; is that right?

5 A That's right.

6 Q. And O-U-D stands for opioid use
7 disorder; is that right?

8 A Yes.

9 Q. What data did Edlund and colleagues use
10 in conducting this study?

11 A They used health claims data from five
12 health claims databases.

13 Q. How did Edlund and colleagues analyze
14 that health claims data?

15 A They constructed variables that
16 represented the dose and duration of opioid use
17 among people who had a claim for a prescription
18 opioid and evaluated the subsequent opioid use
19 disorder diagnosis in the claim.

20 Q. Did Edlund study patients who had not
21 received prescription opioids or have opioid use
22 disorder in the period before they received an
23 opioid?

24 A Yes.

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Q. What did Edlund and his colleagues find?

A They found that there was an increased -- a dose-response relationship essentially between dose and duration of prescription opioid use and incident opioid use disorder.

Q. Did Edlund quantify that dose-response relationship?

A Yes.

Q. This next slide, can you explain to the Court what it shows on -- what it shows in general and maybe start with the right-hand side?

A On the right-hand side are the odds ratios which is a measure of association for the association between prescription opioid use. In this case a greater -- among those with a greater than 90-day supply and the odds ratio for opioid use disorder compared to those who did not receive a prescription opioid.

Q. So let's just look at one of these bars. On the right-hand side, the red bar, it says "high dose" and under that "122.45." What does that mean?

A That means that those who received a high dose of prescription opioids for greater than 90 days had 122.45 higher odds of opioid use

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disorder compared to those who did not receive a prescription opioid.

Q. Is that a strong association?

A Yes.

Q. And then we look at -- if you would look with me at the yellow bar, two bars over from the red bar, it says "low dose" and then "14.92." Do you see that?

A Yes.

Q. What does that show?

A The low dose here were those who were prescribed 136 milligrams per day, again, among those with a greater than 90-day supply and shows that those who were on a low dose for greater than 90 days had almost 15 times higher odds of opioid use disorder compared to those with no prescription opioid.

Q. Is that a strong association?

A Yes.

Q. Now, let me ask you, Dr. Keyes, do epidemiologists ever examine individual patient outcomes?

A Rarely.

Q. Why is that the case?

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A One of the fundamental principles of epidemiology is group comparison that we can learn about causation by studying populations rather than individual patients.

Q. Let's look at a second factor that we had on the slide a moment ago, temporal relationship. Can you explain to the Court what that means?

A Typically for a causal relationship to be present, the exposure has to precede the cause.

Q. So you're looking at whether one thing --

A Occurred before.

Q. -- occurs before another. Okay. And let's try not to talk over each other.

A I'm sorry.

Q. Sometimes I pause in my questions. So did you apply the factor in this case?

A Yes.

Q. Did you apply it in your expert report?

A Yes.

Q. Let's look at a couple of examples of studies that you analyzed in your report. So this is a slide that is from Demo 46, which we'll hand

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1 out now. Now, this is a study that you described
2 and analyzed in your report; is that right?
3

4 A Yes.

5 Q. It's a study by Cicero in 2014 titled
6 "The Changing Face of Heroin Use in the United
7 States, A Retrospective Analysis of the Past 50
8 Years."

9 What did the researchers do in this
10 study?

11 A The researchers in this study analyzed
12 data on individuals who were in substance treatment
13 programs and asked them questions about their prior
14 substance use.

15 Q. So that methodology that the researchers
16 used asking subjects questions, is that a generally
17 accepted methodology in your field?

18 A Yes.

19 Q. Is it -- is there a consensus that that
20 methodology is reliable?

21 A Yes.

22 Q. What did Cicero and colleagues find in
23 their research?

24 A They found that, that among individuals
25 with heroin dependence, that since the 1990s

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2 prescription opioid use most commonly preceded
3 heroin use in these individuals.

4 Q. I'm showing you now a figure that is
5 from the Cicero study. Can you explain to the Court
6 what this figure shows?

7 A In this figure the authors have
8 separated the decade of first opioid use into
9 decades. So the '60s, '70s, '80s, et cetera, and
10 examined whether prescription opioid or heroin use
11 was the first substance used in each of those
12 decades.

13 Q. And if we look all the way at the
14 right-hand side in the 2010s, what does that show
15 with respect to which comes first?

16 A Since the 2000s and in the 2010s,
17 prescription opioid use was more commonly the first
18 opioid used among the sample.

19 Q. Now, let's look at another study that
20 you analyzed in your report. This is Demo 53. This
21 is a study by Lankenau published in 2011 titled,
22 "Initiation into prescription opioid misuse amongst
23 young injection drug users"?

24	A	Yes.
----	---	------

25	Q. What information or data did Lankenau
----	--

1 and colleagues analyze in performing this study?

2 A Similar to the prior study, there was a
3 questionnaire that was conducted among the sample of
4 injection drug users.
5

6 Q. Did this study show that prescription
7 opioid use precedes heroin use?

8 A Yes.

9 Q. How did the researchers reach that
10 conclusion?

11 A Through the questionnaire by asking
12 individuals about their history of drug use.

13 Q. Now, let's look at this slide which has
14 an excerpt from the study. This says "Nearly
15 three-quarters have been prescribed an opioid in
16 their lifetime which occurred on average at 14.6
17 years old." Did I read that correctly?

18 A Yes.

19 Q. And then below that towards the bottom,
20 it says "Two-fifths reported their own prescription
21 as the source of first opioid misuse which typically
22 occurred at 15.3 years old." Did I read that
23 correctly?

24 A Yes.

25 Q. So does this study show that for a

percentage of the subjects, two-fifths, that they had received an opioid prescription from a doctor before becoming -- before initiating heroin?

A Yes. Before initiating injection drug use.

Q. All right. And that injection drug use specifically was heroin use; is that right?

A Yes. I think most were heroin.

Q. Okay. Let's turn to the third factor. We discussed strong association. What do epidemiologists look for?

A So the strength of association, you know, you're looking for an association that is unlikely to be explained by alternative factors essentially, and that a strong association indicates that the occurrence of the exposure have a large effect on the outcome.

Q. So would it be fair to say that the Edlund study, which we spoke about a moment ago, shows a strong association between prescription opioid use and OUD?

A Yes.

Q. And there were other studies, just to be clear, there were other studies you examined that

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showed strong associations between those two things;
is that right?

A Yes.

Q. Now, let's look at the fourth factor,
replication. How do epidemiologists apply that
factor? Well, first what is that factor?

A With replication you're looking to see
if the same association can be observed in
independent samples from independent investigators
in diverse settings.

Q. Did you do that in this case?

A Yes.

Q. How did you do that in this case?

A By synthesizing the available
literature. I look to see whether the same
association could be observed in different study
designs, in different populations, with independent
studies.

Q. So I just want to be clear. We're
looking at some examples right now of how you
applied each of these factors, but the examples are
not the only examples that you analyzed; is that
right?

A That's right.

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1 Q. Would it be fair to say that in applying
2 these factors, you look at the totality of the
3 scientific literature?
4

5 A Yes.

6 Q. Did you, in your opinion, determine that
7 the association between prescription opioid use and
8 OUD and heroin use has been replicated across
9 numerous studies?

10 A Yes.

11 Q. Let's turn to the fifth factor,
12 biological plausibility. Does plausibility simply
13 mean possible?

14 A Yes.

15 Q. How do epidemiologists like yourself
16 apply the factor of biological plausibility?

17 A We look to see whether an association is
18 consistent with known knowledge about biology and
19 other, you know, pharmacology.

20 Q. What does that mean in the context of
21 prescription opioids and OUD and heroin
22 specifically?

23 A Yeah, there have been -- there is
24 literature around the pharmacology of these
25 different products in heroin and prescription

opioids are pharmacologically similar.

Q. So based on the literature and your experience, you determined that it was biologically plausible for prescription opioid use to cause heroin use; is that right?

A Yes.

Q. Now, let's look at the last factor, alternate explanations. How do epidemiologists apply that factor?

A Through study design and data analysis. For example, controlling for confounding factors would be one way to rule out alternative explanations.

Q. And did you look to see whether that was done in the studies that you analyzed?

A Yes.

Q. And you spoke earlier about the 2015 study that you published on the link between opioid use and misuse. Do you recall that?

A Yes.

Q. And in that study in 2015, how did you and your colleagues account for alternative explanations for confounding factors?

A We controlled for factors that would be

1 alternative explanations of the association,
2 specifically controlled for them.

3 Q. And, for example, I think you mentioned,
4 as an alternative explanation, prior addiction or
5 mental health issues; is that right?

6 A That's right.

7 Q. Now, these factors that we've been
8 discussing right now, and Justice Garguilo stole my
9 thunder. I was going to ask you about where they
10 come from and if there is a person associated with
11 them, and is that Bradford Hill.

12 Are these factors commonly described as
13 the Bradford Hill factors?

14 A These are among the Bradford Hill
15 factors, yes.

16 Q. So there are a few more that you didn't
17 talk about today?

18 A Yes.

19 Q. Would it be fair to say that the ones we
20 have talked about are the most important factors
21 that you used in your work on this case?

22 A Yes.

23 Q. And can you briefly explain what the
24 purpose of the Bradford Hill factors is in
25

1 epidemiology?

2
3 A Yes. It's a framework for, for
4 synthesizing literature and coming to conclusions
5 about whether the evidence is consistent with the
6 causal relationship.

7 Q. So by applying those factors, can
8 epidemiologists go from reviewing and synthesizing a
9 body of literature to forming a causal inference?

10 A That's right.

11 Q. Now, I'd like to briefly go over the
12 nuts and bolts of how you applied your methodology
13 in this case.

14 How did you go about this literature and
15 review synthesis that you performed? Where did you
16 start?

17 A I started with PubMed, which is a search
18 engine that is commonly used in my field to elicit a
19 set of articles that were germane to the topic under
20 consideration.

21 From there I also looked at reference
22 lists and kind of drew the body of literature from
23 these initial search criteria. And I also included
24 gray literature that I know of, what we call the
25 gray literature, which is not necessarily

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peer-reviewed articles, but, you know, CDC reports and other governmental reports that are available, publicly available but not might not be peer-reviewed.

Q. So did you also use your background knowledge as someone who specializes in substance abuse disorders in your data and literature review and synthesis?

A Yes.

Q. So you mentioned PubMed. That's a database that is maintained by the federal NIH; is that right?

A Yes.

Q. So from those searches that you did in PubMed, approximately how many articles did you end up reviewing?

A Approximately 400 or so.

Q. What were you looking for in that body of literature?

A I was looking for publications that were specific to the relationship that I was observing. And I was looking for scientific rigor, and I was evaluating them based on the factors that we've outlined.

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1
2 Q. When you say that you were looking for
3 scientific rigor, were you looking at the entirety
4 of each of these studies that you reviewed?

5 A Yes.

6 Q. So you didn't just look at the abstract
7 and then form an opinion about that study; is that
8 right?

9 A That's right.

10 Q. You looked at the underlying methodology
11 that the researchers in each of the studies that you
12 reviewed applied; is that right?

13 A Yes.

14 Q. You mentioned some data sources. You
15 mentioned the CDC. That's the Centers for Disease
16 Control; is that right?

17 A Yes.

18 Q. Did you, in your work on this case,
19 review and analyze and use mortality data from the
20 CDC?

21 A Yes.

22 Q. And did that mortality or death data
23 relate specifically to opioid overdose deaths?

24 A Yes.

25 Q. Did you review any data for this case

1 that came from sources at the State of New York?

2 A Yes.

3 Q. Can you briefly explain, describe the
4 New York State data that you reviewed in this case?

5 A Yes. I primarily relied on the state's
6 opioid dashboard, which is a public facing site that
7 produces available information on opioid-related
8 harms at the county level and the state level.

9 Q. And did you also review opioid reports
10 from, from the State of New York?

11 A Yes.

12 Q. And those are regular reports that the
13 New York State Department of Health publishes; is
14 that right?

15 A That's right.

16 Q. Did you also review data and information
17 that was provided to you by the Plaintiffs in this
18 litigation, the State of New York and Nassau and
19 Suffolk Counties?

20 A Yes.

21 Q. And you relied on some of that data in
22 forming your opinions in this case; is that right?

23 A Yes.

24 Q. Now, I want to focus on the opioid death
25

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1 data. You got some opioid death data from Suffolk
2 and Nassau Counties; is that right?

3 A That's right.

4 Q. What, if anything, did you do to look to
5 see whether that data was reliable?

6 A I examined whether it was consistent
7 with other sources that were produced, for example,
8 by the state.

9 Q. Did you talk to anyone? Did you do any
10 interviews with anyone in either Nassau or Suffolk
11 County?

12 A Yes. I spoke to people in the Medical
13 Examiner's office in both counties.

14 Q. And why did you do that?

15 A I wanted to confirm what the methodology
16 was for designating a death as an overdose, for
17 example.

18 Q. And we'll look at this in a few minutes,
19 but were you looking to see whether the underlying
20 data that you used in forming your opinions about
21 the relationship between opioid supply and harms
22 like opioid overdose deaths, whether the underlying
23 data was reliable?

24 A That's right.

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Q. In your work on this case, did you also review rates of prescribing of prescription opioids?

A Yes.

Q. And did you do that in -- in reviewing studies that analyzed that sort of data?

A Yes.

Q. Now, in this last section of this examination, I'd like to discuss how you applied your methodology in reaching your opinions.

THE COURT: Doctor, is this your methodology or the Bradford Hill methodology that you applied?

THE WITNESS: I would say it fits into both. You know, the Bradford Hill methodology is sort of a larger set of criteria to use when looking at a body of literature, but, you know, the reliability of the underlying data is one of those factors. And so --

THE COURT: Did I hear correctly, you indicated that you applied six of the criteria of the Bradford Hill methodology?

THE WITNESS: Yes.

THE COURT: Is there nine?

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THE WITNESS: There are nine.

BY MR. REISMAN:

Q. Would it be fair to say that you applied all of the factors, but the six that we've just discussed are the most important factors for purposes of explaining your methodology today?

MR. SCHMIDT: I'll object to his feeding testimony to the witness, leading.

THE COURT: Just do me a favor. Take the mask off for a second. What's the objection?

MR. SCHMIDT: Sorry. I will object to that one as leading because he's feeding testimony to the witness.

THE COURT: Rephrase the question. I'm not going to consider the answer. Rephrase the question, and then I'll consider the answer.

BY MR. REISMAN:

Q. Dr. Keyes, in your methodology in this case, did you apply all of the Bradford Hill factors?

A Generally, if I can give an example, I think it would be helpful.

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THE COURT: Go ahead. Give me an example.

THE WITNESS: So another Bradford Hill criteria, for example, is analogy. An analogy is, you know, not necessarily the, you know, whether the evidence is consistent with other associations in the literature that aren't germane to the one that you're considering. And I used analogy in my report.

I just didn't consider it to be among the most, you know, kind of important and compelling factors that drove my opinions, but certainly there are in my report analogies in other, in other literatures, and that would be a Bradford Hill criteria. So that's an example.

THE COURT: Next question.

BY MR. REISMAN:

Q. Did you use the name Bradford Hill? Does it appear in your report anywhere?

A No.

Q. But you did use the principles, the factors that Bradford Hill described in your report;

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is that right?

A That's right.

Q. Now, we're going to move on in this last section to talking about your opinions and how you got from your methodology to your opinions. Does this slide summarize your opinions at a high level in this case, the opinions relating to causation?

A Yes.

THE COURT: Do you have a copy of that slide on paper?

MR. REISMAN: We can make one.

THE COURT: I'll move it. We can see it this way. Thank you.

BY MR. REISMAN:

Q. So the first one, Dr. Keyes, is use of prescription opioids increases the risk of opioid use disorder and abuse of illicit opioids such as heroin and fentanyl; is that right?

A Yes.

Q. The second is the increased supply of prescription opioids since the 1990s led to an increase in rates of opioid use disorder, opioid overdose deaths, and other harms. Did I read that correctly?

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A Yes.

Q. And the third here is marketing of prescription opioids increases prescribers likelihood of prescribing opioids in the future; is that right?

A Yes.

Q. Now, just so we're all clear, your expert report in this case contains other opinions; is that right?

A Yes.

Q. But we're focusing for purposes of today's hearing on these three, okay?

A Okay.

Q. Now, the first one, can you explain to the Court what your basis for that opinion is?

A Yes.

Q. What methodology did you use to reach that opinion?

A I reviewed the literature on the association between prescription opioid use and opioid use disorder as well as these other outcomes, and determined that the literature was consistent in showing that prescription opioid use increased the risk or increased the probability of occurrence of

these outcomes.

Q. In your report you estimated the prevalence of opioid use disorder that is arising out of opioid use; is that right?

A Prescribed opioid use, yes.

Q. So you estimated that prevalence; is that right?

A That's right.

Q. Did you rely, in part, for those prevalence estimates on the Vowles study?

A Yes.

Q. So let's look at this a bit more closely. This is Demo 58. Now, before we get into the studies, what is prevalence?

A Prevalence is the total burden of an outcome in a population.

Q. So what would that mean in the opioid context?

A Prevalence would be the number of people who have opioid use disorder in a given sample or population divided by the total number of people in that population.

Q. Do epidemiologists use prevalence estimates to draw causal inferences?

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A Yes.

Q. Can you explain to the Court why it's appropriate for epidemiologists to do that?

A Oftentimes the total burden of a health outcome has important public health implications. So we examine prevalence as an indicator of total harm.

Q. Is that true in the context of opioids?

A Yes.

Q. So this study by Vowles, it's titled, "Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis;" is that right?

A Yes.

Q. Now, earlier you mentioned your work on the federally-funded and HEALing Communities study. Do you recall that?

A Yes.

Q. In your work on that study, have you used this Vowles study in any way?

A Yes. It's one of the studies that we used in terms of our synthesis and literature reviewed to inform mathematical parameters.

Q. Can you briefly explain how you and your

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colleagues on the study used this Vowles article in developing your work on HEALing Communities?

A Sure. We are developing a mathematical model of the transition in New York State from opioid use to disorder to overdose and treatment and in mathematically modeling the transition from opioid use to opioid use disorder, we relied on Vowles and systematic reviews to inform what proportion of our mathematical agents should transition in New York State.

Q. What is a systematic review?

A A systematic review is typically a paper that examines a whole body of literature and comes to a conclusion from it.

Q. How many studies did Vowles and colleagues analyze in their systematic review?

A 38.

Q. And they did that to reach conclusions about the prevalence of opioid misuse, abuse, and addiction arising out of the use of prescription opioids for treating chronic pain; is that right?

A That's right.

Q. Now, this systematic review methodology that this particular study employed, is that a

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generally accepted methodology in your field?

A Yes.

Q. Is this Vowles study, which analyzed 38 underlined studies, generally accepted in your field as reliable?

A Yes.

Q. Can you explain to the Court why this study is generally accepted as reliable?

A Sure. I think the study is generally accepted as reliable because the methods are rigorous and transparent and the underlying studies are well described.

Q. Now, you used this report to generate your own estimates regarding the prevalence of opioid use disorder arising out of prescription opioid use for chronic pain; is that right?

A That's right.

Q. This next slide is Figure 1 from your report which we handed out a few minutes ago. Can you explain to the Court generally what this slide shows?

A These are circles. The broader circle denoting that you got a, you know, a total population of people who are treated with opioids.

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Within that, there will be a subset who have opioid use disorder ranging from mild to severe disorder.

Q. So let's stop right there. So that middle circle, which is peach colored, it says "Opioid use disorder from mild to severe, 21 to 29 percent;" is that right?

A That's right.

Q. Now, these are estimates that you derived from Vowles; is that right?

A Um-hm, yes.

Q. Did Vowles use the term "opioid use disorder"?

A No.

Q. Where did you get that term from?

A The Diagnostic and Statistical Manual of Mental Disorders.

THE COURT: The DSM?

THE WITNESS: The DSM.

BY MR. REISMAN:

Q. And so that DSM, is it sometimes referred to as the DSM-5, the current version?

A Yes.

Q. Is the DSM-5 used in epidemiology?

A Yes.

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1
2 Q. So is it fair to say that you took the
3 analysis about prevalence that Vowles had and you
4 mapped onto the DSM-5?

5 A That's right.

6 Q. And so that's how you got to that 21 to
7 29 percent figure for OUD from mild to severe; is
8 that right?

9 A That's right.

10 Q. And then the inner circle says "Opioid
11 use disorder from moderate to severe, 8 to 12
12 percent;" is that right?

13 A Yes.

14 Q. And with respect to both of those
15 categories, again, you -- did you take the analysis
16 from Vowles and map that onto the DSM-5?

17 A Yes.

18 Q. So can you explain to the Court why it
19 was appropriate for you to do that as an
20 epidemiologist?

21 A That's commonly done in epidemiology
22 when we're synthesizing literature and trying to
23 draw comparisons of cross studies.

24 Q. So the underlying studies in Vowles,
25 what did they consist of? What methodology did

1 those underlying studies use?

2 A Predominantly they use questionnaires
3 that were given to patients to assess different
4 symptoms related to opioid use disorder.
5

6 Q. So in the systematic review that Vowles
7 performed, Vowles had to map or integrate various
8 questionnaires, various types of questionnaires that
9 the underlying studies used; is that right?

10 A Yes.

11 Q. And to map Vowles onto the DSM-5, you
12 did that same sort of analysis; is that right?

13 A That's right.

14 Q. Now, you mentioned questionnaires and
15 the DSM-5. Let's look at an example of what you
16 did.

17 So this chart, it's not in your report.
18 This is for demonstrative purposes. This is -- this
19 shows an example of your mapping of one of the
20 underlying questionnaires in a study analyzed by
21 Vowles to the DSM-5; is that right?

22 A That's right.

23 Q. What does the right-hand side of the
24 table show?

25 A These are questions from the screener

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and opioid assessment for patients with pain.

Q. And what is that used for?

A That is commonly used in clinical studies to assess whether patients are likely to have a problem with their opioid prescription.

Q. And does having a problem with their opioid prescription sometimes include opioid misuse?

A Yes.

Q. Does it sometimes include opioid use disorder?

A Questions that are consistent with opioid use disorder, yes.

Q. So on the right-hand side, you have some questions that are contained in the actual questionnaire used in some of the studies analyzed by Vowles; is that correct?

A Yes.

Q. And what does the left-hand side of that table show?

A These are criteria from the DSM-5 for opioid use disorder.

Q. And that's the current version of the DSM; is that right?

A That's right.

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1
2 Q. So the first one is opioids are often
3 taken in larger amounts for over a longer period
4 than was intended; is that right?

5 A Yes.

6 Q. And so in your work in mapping Vowles to
7 the DSM-5, you looked to see whether questions in
8 the underlying questionnaires in the studies mapped
9 onto DSM-5 criteria; is that right?

10 A That's right.

11 Q. And this is just an example of two DSM-5
12 criteria for which you performed this mapping
13 analysis; is that right?

14 A That's right.

15 Q. How many criteria does a person need to
16 meet in order to receive a diagnosis of mild opioid
17 use disorder?

18 A At least two.

19 Q. So if a person meets these two criteria
20 that are shown on this slide, is it your
21 understanding that a clinician would diagnose that
22 person with mild opioid use disorder?

23 A In most cases, yes.

24 Q. Now, with respect to your prevalence
25 estimates of OUD that you derived from the Vowles

1
2 systematic review, did you do anything to assess the
3 reliability of your estimates?

4 A Yes.

5 Q. Can you tell the Court what you did?

6 A I identified a study that was published
7 after the Vowles study that used DSM-5 criteria in
8 assessing the prevalence of OUD in another sample of
9 people being prescribed opioids.

10 And that study came up with very similar
11 prevalence estimates as Vowles. And so that was an
12 indicator that Vowles was a reliable study to use to
13 estimate the prevalence of OUD.

14 Q. Now, Dr. Keyes, are you aware that the
15 Defendants in this case criticize you for not
16 addressing in your report a study that was published
17 last year by a researcher named McCabe?

18 A Yes.

19 Q. Now, before we get to that McCabe 2019
20 study, I'd like to ask you, again, roughly how many
21 studies did you rely on to form your opinions
22 regarding the causal relationship between
23 prescription opioid use and opioid use disorder?

24 A Dozens.

25 Q. And in your report you do cite studies

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that were published by McCabe prior to 2019; is that right?

A Yes.

Q. Let's look at this one. This is Demo 55. Is the title of this study Trends in Medical and Nonmedical Use of Prescription Opioids Among US Adolescents: 1976 to 2015?

A Yes.

Q. It was published in 2017; is that right?

A Yes.

Q. How did McCabe and his colleagues conduct this 2017 study?

A So these data are drawn from Monitoring the Future, the study that we discussed earlier. And they use questionnaires of adolescents on medical and nonmedical opioid use every year since 1976 through 2015.

Q. In this study that we're looking at, what were the primary findings of the researchers?

A The primary findings were that medical and nonmedical use of prescription opioids are highly correlated.

Q. Can you explain in laypersons terms what that means?

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A It means that there's a lot of overlap between students who use opioids nonmedically and those who report opioid use medically.

Q. Did the study that McCabe published in 2017 reach any conclusions about which came first, whether it was prescription opioid medical use first or nonmedical use first?

A Yes. Among the students who used both medically and nonmedically, medical use is more likely to precede the nonmedical use.

Q. And, again, the medical use is taking a prescription opioid because a doctor told you to?

A That's right.

Q. So this study concluded that that group of medical users used medically before using nonmedically; is that right?

A They were more likely to, yes.

Q. Now, let's look at the 2019 study that McCabe published. This is Demo 54. This McCabe 2019 study is titled, "A Prospective study of nonmedical use of prescription opioids during adolescence and subsequent substance use disorder symptoms in early midlife;" is that right?

A That's right.

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2 Q. Now, before you filed your expert report
3 in this case, did you review this study?

4 A Yes.

5 Q. How did you know about it?

6 A I'm generally familiar with studies that
7 are published for Monitoring the Future given my
8 close affiliation with the study.

9 Q. Why did you not discuss this study in
10 your report?

11 A Opioid use disorder wasn't an outcome of
12 the study, so it didn't seem particularly relevant
13 to the, to the investigation that I was doing.

14 Q. You mean to the assignment that you had
15 in this case; is that what you mean?

16 A That's right, yes.

17 Q. Did this 2019 study repudiate the
18 findings that the 2017 study made?

19 A No.

20 Q. Now, why did you come back to this
21 study? Why -- did you come back to this study and
22 review it after you filed your report?

23 A Yes.

24 Q. Does this study -- reviewing this 2019
25 study now, does it change your opinions in any way?

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A No.

Q. What is the primary finding in your opinion of this study?

A The primary finding is that individuals who use prescription opioids have an increased risk of substance use disorders at age 35.

THE COURT: Okay. There's an objection. Go ahead.

MR. SCHMIDT: Your Honor, I didn't object before because this is undisclosed, and she's just been saying why it's undisclosed. Now she's giving substantive undisclosed opinions about it. We object on that basis. It's not on her reliance list. It's not discussed in her report.

THE COURT: Mr. Reisman?

MR. REISMAN: This was used by Mr. Schmidt as an exhibit during Dr. Keyes' deposition back in January. It's completely appropriate for her to be testifying about it now.

MR. SCHMIDT: She's giving a new undisclosed --

THE COURT: Say it again.

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MR. SCHMIDT: That's exactly accurate.

I was the first one to show it to her. She's giving now a new undisclosed opinion about it.

THE COURT: Okay. During the examination, was the doctor examined in connection with this -- in connection with we'll call it this report?

MR. SCHMIDT: During my examination, yes, but she didn't give the opinions that she's now giving about it.

THE COURT: That's what impeachment is all about.

MR. SCHMIDT: That's what expert witness disclosures are all about.

THE COURT: Overruled. Go ahead.

BY MR. REISMAN:

Q. So I just want to make sure we have on the record, Doctor, your opinion about the primary finding of this study. Can you say that again?

A Yes. The primary finding of the study is that adolescents who report prescription opioid use have an increased risk of substance abuse disorder at age 35.

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Q. And that is adolescents who use medically or nonmedically?

A Primarily those who use nonmedically.

Q. Did the study reach any conclusions about whether medical users of opioids later become nonmedical users of opioids?

A I'm sorry. Can you repeat the question?

Q. Did the study reach any conclusions about whether medical users of opioids later become nonmedical users of opioids?

A I don't believe that's covered in this paper.

Q. Does it matter which comes first, medical use of opioids or nonmedical use?

A For the purposes of developing a substance use disorder, exposure to opioids is the primary risk factor.

THE COURT: So it doesn't matter? Okay.

THE WITNESS: No.

BY MR. REISMAN:

Q. Is the answer to the question no?

A Correct.

Q. Now --

THE COURT: By the way, I think there

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was a finding in the MDL by Judge Polster.

MR. REISMAN: Yes, your Honor.

BY MR. REISMAN:

Q. And speaking of which, I want to turn now to talking about your opinions about the causal relationship between prescription opioid use and heroin use. Is that sometimes called the gateway effect?

A Yes.

Q. Now, in forming your opinions about this aspect of the gateway effect, you reviewed a large number of studies; is that right?

A That's right.

Q. So the studies fell in several categories. You reviewed 16 studies that found that individuals who use prescription opioids nonmedically have significantly higher rates of heroin use than those who do not; is that right?

A That's right.

Q. And those studies that you reviewed controlled for other factors; is that right?

A Many of them did, yes.

Q. And as we saw earlier with Cicero, studies show that up to 80 percent of individuals

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who used heroin in the last 20 years started their opioid use with prescription opioids; is that right?

A That's right.

Q. Another type of evidence that you relied on are studies that were conducted here in New York showing that pathway; is that right?

A Yes.

Q. And then finally we have on this slide the analysis of studies evaluating the effectiveness of prescription drug monitoring programs.

Can you just briefly explain to the Court the significance of the role of prescription drug monitoring programs in heroin use?

A Yes. So prescription drug monitoring programs have been introduced in New York to, to provide a greater check on the opioid supply and opioid prescribing and has resulted in fewer opioid prescriptions to many people who have become dependent on prescription opioids.

And numerous studies have now shown that when the opioid supply is restricted, that there is a transition among individuals with high levels of prescription opioid use to heroin.

Q. So is it fair to say that even though

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opioid prescribing has gone down in the last few years, heroin use has gone up?

A Yeah, that's correct.

Q. And do the studies about the impact of prescription drug monitoring programs or PDMPs draw a connection between prescription opioid use and heroin use?

A Yes.

Q. And so your methodology in this case was to look at this body of literature that looked at different factors in the link between prescription opioid use and heroin use; is that right?

A That's right.

MR. ERCOLE: Your Honor, this is Mr. Ercole. I'm just going to object. At this point in time, counsel is literally leading opinions to the witness on these issues.

THE COURT: So you're suggesting counsel is permissively leading; is that it?

MR. ERCOLE: Yes, your Honor.

THE COURT: All right. Sustained.

Don't lead.

There's times you can lead on

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preliminary matters. When we get down to substance, try not to.

MR. REISMAN: Understood.

THE COURT: Thank you.

BY MR. REISMAN:

Q. Let's look at several other studies that you analyzed in forming your opinions on this issue. This is Demo 57.

This is a study titled, "Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States;" is that right?

A That's right.

Q. And it was authored by Muhuri, M-U-H-U-R-I, in 2013?

A Yes.

Q. What did the researchers do in this study?

A They analyzed data from the National Survey of Drug Use and Health, which is conducted annually in the United States. And they used data from 2002 to 2011 to examine the risk of heroin initiation based on prior nonmedical opioid use.

Q. What did they find?

A They found that prior nonmedical opioid

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use increased the risk of heroin initiation.

Q. Did they make any finding about the percentage of heroin users that initiated their opioid use with prescription opioids?

A Yes.

Q. What was that finding?

A The prevalence of heroin initiation was 3.6 percent for the incidents -- excuse me -- the incidents of heroin initiation.

Q. What percentage of heroin users, according to this study, began opioid use with prescription opioids?

A 80 percent.

Q. Now, do all prescription opioid users become heroin addicts?

A No.

Q. And you a mentioned a statistic a moment ago, that 3.76 percent?

A Yes.

Q. Can you explain, again, what that means?

A That means that 3.6 percent of people who use prescription opioids nonmedically progressed to initiate heroin within five years.

Q. Is that a significant number?

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A Yes.

Q. Can you explain why that is significant?

A Heroin use is relatively rare in the population. And so 3.6 percent represents hundreds of thousands of people.

Q. Let's look at the next study here. It's Demo 45. This is a study titled, "Non-medical use of prescription opioids is associated with heroin initiation among US veterans: a prospective cohort study;" is that right?

A Yes.

Q. What did the researchers do in this study?

A In this study they used a cohort of veterans who had been ascertained at clinics in major cities in the U.S. and examined whether nonmedical use of prescription opioids was associated with heroin initiation.

THE COURT: The report indicates they use a multivariable Cox regression model.

THE WITNESS: That's correct.

THE COURT: What is that?

THE WITNESS: That is a type of regression model that accounts for time to

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event data. So if you want to study the time to heroin initiation, you have to have a regression model that allows you to model that out comp with a Cox proportional distribution.

THE COURT: Thank you.

BY MR. REISMAN:

Q. What data did the researchers use in this study?

A They used Veterans Health Administration infectious disease and primary clinic data.

Q. Can you just be a little more specific? Were they using surveys or other types of data?

A Yes. They did use surveys.

Q. Okay. So this study used surveys, and you mentioned that in the Lankenau study surveys were also used; is that right?

A That's right.

Q. And then the Muhuri study as well; is that right?

A That's right.

Q. And so is using surveys on a question like this the link between prescription opioid use and heroin use a reliable methodology?

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A Yes.

Q. What was the finding of the researchers in this study?

A The finding was that nonmedical use of prescription opioids was associated with heroin initiation.

Q. And that's in a population of veterans?

A That's right.

Q. You expressed an opinion in this case that prescription opioid use is linked to heroin use and subsequently to fentanyl use; is that right?

A Yes.

Q. What is fentanyl?

A Fentanyl is a highly potent synthetic opioid.

Q. In terms of MMEs, approximately what is the MME equivalent of fentanyl?

A I believe it's 50 to 100 times more potent depending on the fentanyl analog that's being analyzed.

Q. Now, this slide is P-23781. Is this document that we're looking at a report from the CDC about fentanyl in 2016?

A Yes.

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Q. Did you discuss this in your report?

A Yes.

Q. What does this, what does this report say about fentanyl?

A That fentanyl has been adulterated into the heroin and prescription opioid supply in the United States.

Q. So how did you use this report in forming your opinions about the link between prescription opioid use, heroin use, and fentanyl use?

A Because fentanyl has been mixed or contaminated in the heroin supply, my opinion is that the extent to which prescription opioid use is causally associated with heroin use, it's similarly causally associated with heroin use that has been tainted with fentanyl.

MR. HERMAN: Your Honor, this is Steve Herman for the pharmacies, and I apologize for the late objection, but I believe the question was: How was this used in your report?

And if I'm not mistaken, I believe this is a material that was considered after the

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report. And so I would just like to object and to also note that I believe we filed a letter objecting to the late disclosure of the supplemental materials considered list.

THE COURT: First of all, don't ever apologize for objecting. Part and parcel of your job is to protect the record.

Mr. Reisman, did you hear what he said?

MR. REISMAN: Yeah. With all due respect, Mr. Herman is wrong. This is in her report. He's referring to another document we'll get to in a minute, but this one is in her report.

MR. HERMAN: I apologize; obviously, that list came in later.

THE COURT: You don't have to apologize for objecting; you don't have to apologize for not. It's okay.

Go ahead.

BY MR. REISMAN:

Q. So, Dr. Keyes, let me ask you this question. So is fentanyl seen in the world out there as in other substances besides opioids like cocaine and so on?

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A Yes.

Q. Is it your opinion in this case that every single overdose death associated with fentanyl is attributable to prescription opioids?

A No.

Q. What percentage of fentanyl-related deaths are attributable to prescription opioids in your opinion?

A My opinion is that in terms of heroin-related deaths that approximately 80 percent.

THE COURT: He asked about fentanyl.

THE WITNESS: Right. So of those that are not -- I would divide the two between heroin-related deaths and non heroin-related deaths.

Among the non heroin-related deaths, certainly there is overlap between, you know, cocaine and methamphetamine and other substances and opioid use.

And so certainly some of those would be attributable, but to a less extent than heroin-related deaths.

So I don't have a specific number for all fentanyl deaths.

BY MR. REISMAN:

Q. Let's focus on heroin-related deaths.
What percentage of heroin -- let me strike that.
Let me rephrase.

What percentage of fentanyl-tainted
heroin deaths are attributable to prescription
opioids?

A I would estimate that about 75 to 80
percent.

Q. Why is that?

A Because 75 percent to 80 percent of
those individuals are likely to have begun with --
begun their opioid use with prescription opioids.

Q. And with respect to fentanyl-related
deaths for which there is no heroin or opioid
involved, you mentioned that you believed that there
is a connection to opioids. Can you explain what
you meant by that?

A Sure. People who use other substances
such as cocaine and methamphetamine, it often
co-occurs with opioids. So there's not no
connection. All of these drugs often co-occur among
individuals.

Q. Now we're going to look at -- sorry.

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There's a little delay in advancing slides.

THE COURT: It's okay.

BY MR. REISMAN:

Q. Let's move to the third opinion that you expressed in this case or that was summarized earlier.

The increased supply of prescription opioids since the 1990s led to an increase in rates of OUD. Actually, it's the second opinion. Let me ask you this first.

Did the supply of prescription opioids in New York and in Nassau and Suffolk Counties increase beginning in the 1990s?

A Yes.

Q. Can you explain to the Court what your basis for that statement is?

A I reviewed data on the distribution of opioids as well as data on pharmacy dispensing of opioids.

Q. What data did you review?

A The ARCOS data as well as IQVIA.

Q. Can you tell the Court what ARCOS data is?

A ARCOS is a database that measures the

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distribution of medication, pharmaceutical medication in the United States.

THE COURT: We asked the former chief of the FDA what ARCOS stands for. He didn't have the answer. Do you?

THE WITNESS: Yes. It's the Automated -- I might get it wrong, but the Consolidated Order System. And I don't remember -- I got three out of five.

BY MR. REISMAN:

Q. Is it the Automation of Reports and Consolidated Orders System?

A That's right.

Q. So ARCOS measures -- is it fair to say that ARCOS measures the distribution of opioids?

A Yes.

Q. How did you go about reviewing ARCOS data for this case?

A I relied on studies, published studies that have examined the association between distribution of opioids and opioid-related harm or studies that examined the distribution more generally as well.

Q. You mentioned IQVIA a moment ago; what

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1 is that?

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3 A That is a database that measures the
4 pharmacy dispensing of medication.

5 Q. How did you go about reviewing IQVIA
6 data?

7 A Similarly. I reviewed the peer-reviewed
8 literature that included IQVIA data on opioids.

9 Q. So this slide here that you have on the
10 screen is Demo 59. This is a study titled, "Trends
11 and Patterns of Geographic Variation in Opioid
12 Prescribing Practices by State, United States, 2006
13 through 2017;" is that right?

14 A Yes.

15 Q. Is this a study that you analyzed and
16 relied upon in forming your opinions about the
17 opioid supply?

18 A Yes.

19 Q. Can we look at the pull out from the
20 slide? It says at the end, "In 2017 pharmacies
21 filled enough opioid prescriptions to theoretically
22 provide every US resident with 5 milligrams of
23 hydrocodone bitartrate every four hours around the
24 clock for three weeks;" is that right?

25 A That's right.

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Q. Now, in your report did you conclude that the empirical literature demonstrates a strong and statistically significant association between the opioid supply and the increase in prescription opioid deaths?

A Yes.

Q. You mentioned that you rely on peer-reviewed literature for your opinions about the increase in supply.

Let's look at this study. This is Demo 62. This is a study titled, "U.S. county prevalence of retail prescription opioid sales and opioid-related hospitalizations from 2011 to 2014"?

A That's right.

Q. Now, you mentioned a moment ago that you have reviewed studies that analyze ARCOS data. Is this one of those studies?

A Yes.

Q. What was the conclusion of the researchers in this study?

A They concluded that there was a positive and significant relationship between the distribution of opioids and opioid-related hospitalization rates.

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Q. Did they quantify that relationship?

A Yes.

Q. How so?

A They included the, the percentage increase in hospitalization rates that occurs with each increase in opioid sales per 10,000 people.

Q. And what was that percentage?

A 90 percent.

Q. Did you do any work to extrapolate the results of this study to New York State and Nassau and Suffolk Counties?

A Yes.

Q. What did you do?

A I compared -- I extracted from publicly available records opioid distributions and opioid related hospitalizations just so I could determine whether the direction and magnitudes of the relationships were similar.

Q. Does this next slide show the results of your extrapolation?

A Yes.

Q. Are these figures that are shown in this table contained in your report in this case?

A Yes.

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Q. So based on this Gherlner study published last year, you extrapolated and determined the approximate number of prescription opioid pills per resident in the State of New York and Suffolk and Nassau Counties per year; is that right?

A Yes.

Q. And you were also able to estimate hospitalization and neonatal abstinence rates; is that right?

A That's right.

Q. What is neonatal abstinence?

A That is a collection of symptoms that occurs among newborns that are consistent with drug withdrawal; for example, from opioids.

Q. This next slide, is this a figure that is contained in your expert report, Figure 5?

A Yes.

THE COURT: Excuse me. How much more time?

MR. REISMAN: Ten minutes.

BY MR. REISMAN:

Q. What does this show?

A This shows overdose death rates in the U.S., in New York State, in Nassau and Suffolk

County as extracted from the CDC WONDER data from 1999 through 2017.

Q. Does this show calculations that you made using data from various sources at the federal and state level?

A Yes.

Q. Why do the trends increase a lot beginning in 2013 and 2014?

A That is around the time that the -- that the opioid supply in the United States became contaminated with fentanyl.

Q. So before that, the trends of overdose death rates increased, but then they increased even more after that point when fentanyl showed up in the heroin supply; is that right?

A That's right.

Q. I'd like to talk now about the third opinion that we saw on the slide earlier about marketing causation.

And, Dr. Keyes, are you aware that in the federal MDL in Ohio, Judge Polster ruled that you cannot testify about marketing causations, specifically the relationship between marketing of prescription opioids and opioid prescribing?

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A Yes.

Q. Can you tell Justice Garguilo what you did to analyze that relationship for this case?

THE COURT: Since that determination?

MR. REISMAN: Yes.

THE COURT: Go ahead.

THE WITNESS: Yes. I've done a number of things, including, Number 1, I relied on the -- not the marketing materials themselves, but on epidemiological literature and epidemiologists who analyzed the relationship using statistical models that are germane to my field.

And I also, as a Bradford Hill criteria of analogy, analyzed other epidemiological studies that look at similar associations with other products in order to determine whether there was a body of evidence with epidemiological methods that I could rely on.

THE COURT: Okay. Judge Polster -- and correct me if I'm wrong. By the way, Judge Polster, as you know, is the Judge in the federal MDL out of Ohio.

You and a couple of other witnesses on

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this question of marketing causation spent some time discussing your lack of background in the field of let's say pharmaceutical marketing.

THE WITNESS: Yes.

THE COURT: Are you suggesting that the work you have done since that determination addresses that finding? Just yes or no.

THE WITNESS: Yes. I think the work that I've done in the report has addressed the finding.

THE COURT: The gentlemen will cross-examine on that, of course.

BY MR. REISMAN:

Q. So let me ask you this, Dr. Keyes. So is it fair to say that there are two types of marketing causation studies that you analyzed for purposes of your opinion on marketing causation; Number 1 being general studies about the link between marketing and prescribing and, Number 2, specific studies focused on opioids?

A That's right.

MR. ERCOLE: Your Honor, I'm going to object again. It's leading, particularly

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with respect to this question when we are getting into the substance of the opinion.

THE COURT: I'm being scolded by my stenographer, and rightfully so.

Identify yourself before you note your objection so we get you on the record.

So go ahead. This is Mr. So-and-So on behalf of So-and-So. My objection is as follows.

Go ahead.

MR. ERCOLE: Yes, your Honor. My name is Brian Ercole, on behalf of the Teva Defendants, and my objection is that this is -- this particular question was leading.

THE COURT: All right. Rephrase.

BY MR. REISMAN:

Q. So, Dr. Keyes, you mentioned the body of epidemiological literature regarding the link between marketing and prescribing.

Can you describe what that body of literature includes?

A Yes. It includes epidemiologists and other people in the epidemiology field who examined statistically associations using data on -- that are

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germane to marketing and their associations with prescribing and other outcomes.

Q. Does an epidemiologist need to have a background in marketing in order to study the impact of marketing on prescribing?

A No.

Q. To your knowledge, did the epidemiologist who conducted the studies that you reviewed for this case have a background in marketing?

A Not to my knowledge.

Q. What information did those epidemiologists whose work you reviewed for this case use to form conclusions about the impact of marketing on prescribing?

A They used a database that included information on -- that was quantified dollars of marketing, for example. They did not review the actual marketing material.

Q. So we're going to move to the end here and talk about several studies.

THE COURT: A while ago you told me ten minutes. So if you need more time, I'll take a morning break now.

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MR. REISMAN: Why don't we do that?

Yes, please, thank you.

THE COURT: We'll take a 15-minute recess.

(WHEREUPON, a short recess was taken.)

THE CLERK: Come to order. Part 48 is now in session.

THE COURT: Please be seated. Thank you.

THE CLERK: Doctor, I remind you you're still under oath.

THE WITNESS: Thank you.

THE COURT: You may.

MR. REISMAN: Thank you, your Honor.

BY MR. REISMAN:

Q. Dr. Keyes, since Judge Polster issued his marketing causation opinion in the federal opioids MDL, have you become an expert in marketing?

A No.

Q. Let me ask you this. Do epidemiologists study the effect of marketing on prescribing?

A Yes.

Q. What methodology do epidemiologists use to study that link?

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2 A We use the same methodology that we
3 would use for any exposure-outcome relationship.

4 Q. For example?

5 A The same methodology that you would use
6 to study prescription opioid dose and duration with
7 OUD.

8 Q. Are you referring to the Bradford Hill
9 factors, for example?

10 A Yes.

11 Q. So would you look to see if there's a
12 dose-response relationship?

13 A Yes.

14 Q. Would you look to see if there is
15 replication?

16 A Yes.

17 Q. Would you look to see if the studies
18 account for alternative explanations?

19 A Yes.

20 Q. Would you apply other Bradford Hill
21 factors?

22 A Yes.

23 Q. So this is what epidemiologists do; is
24 that right?

25 A That's right.

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Q. Is that what you did in this case?

A Yes.

Q. Since you filed your report in the MDL that Judge Polster addressed, between that time and the time you filed your New York report, did you review and analyze any additional studies regarding the link between marketing of prescription medications generally and prescribing generally?

A Yes.

Q. Now, you looked in particular in your expert report, you analyzed some studies relating to the marketing of opioids and the impact on the prescribing of opioids; is that right?

A That's right.

Q. Let's bring up the next slide, if we can. So this is Demo 50.

Is this the study from Hadland and colleagues in 2017 titled, "Industry Payments to Physicians for Opioid Products, 2013 to 2015"?

A Yes.

Q. Can you briefly tell the Court what data Hadland analyzed in this study?

A Yes. They used data called Open Payments, and this was a database that included

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information on the dollars that were -- the payments to doctors for opioid products.

Q. Do you know who maintains Open Payments?

A I'm not sure off the top of my head.

Q. Is it a federal agency?

A I believe so. I believe it was the result of a -- there was a law that was passed saying that these data had to be made public.

Q. Did Hadland in this study interview doctors?

A No.

Q. Did Hadland review marketing materials?

A Not as far as I know, not based on the published paper.

Q. Let's look at the next study from Hadland and colleagues. This is --

THE COURT: By the way, go back to the last one for one second.

MR. REISMAN: Yes.

THE COURT: It reads: "These findings should prompt the examination of industry influences on opioid prescribing."

It says it should prompt this kind of an examination/investigation.

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Was there a follow-up on that?

THE WITNESS: There were several other studies published from the same data that examines the industry influences.

THE COURT: But the only conclusion is that the findings should prompt an examination.

THE WITNESS: Yes.

THE COURT: Okay. Thank you. By the way, does the article say who was to conduct the examination?

THE WITNESS: That's not specified in the paper.

THE COURT: Okay. Thank you.

BY MR. REISMAN:

Q. So this is Demo 49. I correct myself. It's Demo 51.

Is this study -- was this done, published by Hadland in 2018, a year after -- actually, you know, let's hold this for a moment. And I want to ask you about the prior study.

MR. REISMAN: Can we bring the slide back up. Yeah, if we can skip to the end.

Okay. So, Sal, if you could hand out

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Demo 49.

BY MR. REISMAN:

Q. So is this study that was published in 2018 in JAMA Internal Medicine, is it titled, "Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing"?

A Yes.

Q. And this is the same Hadland who published the study that we just looked at a year earlier; is that right?

A The same first author, yes.

Q. So what did Hadland do in this study in 2018?

A So this study linked two different databases. One is the same Open Payments database that we were -- that was the topic of the American Journal of Public Health paper.

And then they looked at that in association with the Medicare Part D opioid prescriber summary file to correlate the marketing practices with prescription claims for Medicare beneficiaries.

Q. What did Hadland find in this study?

1
2 A They found an association between the,
3 the amount of money that doctors received from
4 opioid manufacturers with subsequent opioid
5 prescribing.

6 Q. The slide that we're showing right now
7 is drawn from the article itself.

8 Can you explain to the Court what this
9 slide shows?

10 A Yes. This is the association between
11 the number of meals received in 2014 and the number
12 of opioid claims in 2015 from those same physicians
13 based on the number of meals that they received.

14 Q. Does it show that the more meals that
15 physicians received from opioid industry sales
16 representatives, the more opioids they prescribed?

17 A Yes. This would be consistent with
18 dose-response.

19 Q. Does this study, the 2018 study mention
20 any specific manufacturers of opioids?

21 A Yes.

22 Q. Which ones?

23 A It mentions the three companies with the
24 highest payment totals: Insys Therapeutics, Teva
25 Pharmaceuticals, and Janssen Pharmaceuticals.

1 Q. Let's move to the last slide, and we
2 already marked this for demonstrative purposes. The
3 study is Demo 51.

4
5 Is this a study that Hadland published
6 last year in JAMA Open?

7 A Yes.

8 Q. And is this one titled, "Association of
9 Pharmaceutical Industry Marketing of Opioid Products
10 With Mortality From Opioid-Related Overdoses"?

11 A Yes.

12 Q. What did Hadland and colleagues do in
13 this study?

14 A So similar to the prior study where
15 different databases were linked, this study used the
16 same Open Payments database and linked it with the
17 CDC WONDER data, the same mortality data that I
18 published in my report.

19 Q. What did the researchers conclude?

20 A They concluded that there was an
21 association between the amount of money spent on
22 opioid marketing and opioid-related harms in terms
23 of prescription opioid overdoses in those same areas
24 that were highly saturated with marketing dollars.

25 Q. So in this Hadland 2019 study, did the

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researchers build on the articles they published in 2018 and 2017?

A Yes.

Q. Did you, in your work on this case, evaluate the marketing materials of any manufacturer Defendant?

A No.

Q. Why not?

A Because that's not part of the epidemiological science that I relied on.

Q. Did Hadland and colleagues in these studies that we just looked at evaluate the marketing materials of any manufacturer?

A It's not in the study.

Q. What did they evaluate?

A They evaluated the Open Payments database.

THE COURT: By the way, these authors in Demo 51, are they epidemiologists or something else?

THE WITNESS: I am familiar with several of the authors who are -- who have Ph.D.s in epidemiology. I don't know the qualifications of all the authors, but many

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of the authors have Ph.D.s in epidemiology.

THE COURT: I'm talking about the people that were listed on 51, Hadland, Rivera-Aguirre, et cetera.

THE WITNESS: Yes.

THE COURT: My question is: Are they epidemiologists?

THE WITNESS: Three out of the four I know are epidemiologists. One is a question mark.

THE COURT: Out of curiosity, which one is it?

THE WITNESS: I don't know the background of Rivera-Aguirre.

THE COURT: Thank you.

BY MR. REISMAN:

Q. Dr. Keyes, in your work on this case and in forming your opinions on marketing causation, did you interview any doctors?

A No.

Q. Why not?

A That's not part of the epidemiological science that I relied on.

Q. To your knowledge did Hadland in these

three opioid studies interview any doctors?

A Not to my knowledge.

Q. Did you review any patient charts in connection with your work on this case?

A No.

Q. Why not?

A Similarly, it's not part of the epidemiological science that I used.

Q. Do epidemiologists draw associations between cause and effect?

A Yes.

Q. Is that what Hadland and colleagues did in these three studies that we just looked at?

A They were looking at associations. And then I think it's up to the epidemiologist reviewing the material to synthesize those associations and draw their own conclusions.

Q. Is it a generally accepted practice in epidemiology to draw causal inferences from studies that in themselves conclude that there is association between cause and effect?

A That's right.

Q. Is that what you did in this case?

A Yes.

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1
2 Q. Dr. Keyes, just a few concluding
3 questions.

4 Was your testimony about the methodology
5 that you used in formulating your opinions in this
6 case based on your training in epidemiological
7 methods?

8 A Yes.

9 Q. And did you apply those methods to all
10 of the opinions that we discussed today?

11 A Yes.

12 Q. Is it a fair summary of your methodology
13 to say that first you assessed whether there is an
14 association between exposure to prescription opioids
15 and harms?

16 A Yes.

17 Q. And is it also fair to say that you then
18 determined whether those associations are causal by
19 reviewing and synthesizing scientific literature
20 using the factors that we've discussed today?

21 A That's right.

22 Q. And did you apply that same methodology
23 to your opinions about the link between opioid
24 supply and harm?

25 A Yes.

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Q. Did you apply that same methodology to the link between marketing of prescription opioids and prescribing of prescription opioids?

A Yes.

Q. Let me ask you one final question, Dr. Keyes. Prior to today, on how many occasions have you testified before a judge as an expert in any case?

A Zero.

MR. REISMAN: Thank you, Dr. Keyes.

Pass the witness.

THE COURT: Thank you.

The attorneys I have listed for examiners on this witness are for the distributors, Mr. Schmidt; manufacturers, Mr. Ercole; and pharmacy, Mr. Herman.

MR. SCHMIDT: Correct as to me, your Honor, Paul Schmidt.

THE COURT: You may.

CROSS EXAMINATION

BY MR. SCHMIDT:

Q. Dr. Keyes, good morning. I'm going to start asking you questions now and then continue into the afternoon, and I'm going to focus on two

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aspects of your opinion; supply and how that relates to harm and what's responsible for supply, and then the gateway view that you've espoused.

Before I do that, I want to start with a few basic points. Is it generally accepted in your field, epidemiology, that something is a cause if the outcome would not have occurred in the absence of that factor, holding everything else constant?

A Yes.

Q. Is it generally accepted in epidemiology that an association does not necessarily equal causation?

A Yes.

Q. In your field, an association means there's some kind of relationship, statistical or otherwise, between two variables, correct?

A That's right.

Q. But that doesn't necessarily tell us that there's a causal relationship in one direction or the other, correct?

A Not necessarily.

Q. It's necessary to rigorously test an association to determine whether the association reflects a causal association, true?

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A Yes.

Q. And in doing that, it's generally accepted in epidemiology that you have to account for other potential causes, correct?

A Generally.

Q. And you'll recall that was one of the factors you cited on Slide 7 of your methodology slide, and I think you described that as a standard factor considering alternative causes, correct?

A Yes.

Q. That's a critical factor in a causation analysis, right?

A It's one among several.

Q. Is it critical?

A Yes.

Q. And it's generally accepted, but you have to consider alternate causes, correct?

A Yes.

Q. Now, you spent some time talking about Bradford Hill, and that being a methodology. That's a methodology that was announced in a speech by Austin Bradford Hill in the '60s, correct?

A Yes.

Q. And I think you acknowledge that that's

1 a term, Bradford Hill, that you never once mention
2 in your report; is that correct?

3 A That's correct.

4 Q. You don't lay out in your report,
5 according to the nine factors of Bradford Hill and
6 how you believe your opinions track against those
7 nine factors, correct?

8 A Correct.

9 Q. And you certainly don't do that if you
10 recall Slide 14 of your presentation, that's where
11 you have the three individual opinions. You
12 certainly don't do that for those three individual
13 opinions. Say, for this opinion, here's how factor
14 one is met, here's how factor 2 is met, here's how
15 coherence is met. Here's how analysis of alternate
16 causes is met, correct? You don't do that?

17 A That's right.

18 Q. There's no mention at all in your
19 report, for example, of something like biological
20 plausibility, correct?

21 A Those words may not be in the report.

22 Q. Now, you do set forth your methodology
23 in your report, correct?

24 A Yes.

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Q. Do you have it handy?

A Yes.

Q. If you look at page 11 of your report, I believe there is a two- or three-page discussion of your methodology for the review of the evidence, correct?

A Yes.

Q. And there's no mention of Bradford Hill in there, correct?

A Not that name.

Q. There's no walk through of Bradford Hill factors one by one in there, is there? Yes or no.

A Not of the Hill factors.

Q. Okay. And you talked about published articles you have on prescription opioids. You've never published an article on prescription opioids that contains one of the three opinions that you stated on Slide 14 that you were shown with Plaintiffs' counsel. You've never published an article setting forth one of those three opinions and specifically invoking Bradford Hill to analyze those opinions, correct?

A I mean, those are two questions, right? The first is --

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1
2 Q. It's a two-part question. Have you
3 published the opinions that you've given us in court
4 in an article that specifically discusses the
5 Bradford Hill factors or even references the
6 Bradford Hill criteria? Yes or no.

7 A The word Bradford Hill specifically?

8 Q. Yes.

9 A Not the word Bradford Hill specifically.

10 Q. Or that walks through each factor one at
11 a time?

12 A The discussion sections of the paper is
13 generally in epidemiology cohered to the types of
14 factors that Bradford Hill outlined in.

15 Q. Can you points me to a paper you
16 published where you give one of the opinions on
17 causation in this case and specifically walk through
18 the various Bradford Hill factors to support that
19 opinion? Yes or no.

20 A No, not at the time.

21 Q. Now, I'd like to turn now to the
22 substance and how that tracks your methodology, and
23 I want to start first with your opinion on supply.
24 I want to talk about the why of supply.

25 Are you aware that the DEA, the Drug

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1
2 Enforcement Administration has publicly gone on
3 record and talked about their role in supply, and
4 they have said that we control the amount produced,
5 bought, sold, and otherwise transferred. Are you
6 aware of that?

7 A I'm not aware of that material.

8 Q. Do you take issue with that DEA
9 testimony that our United States Congress, that DEA
10 controls the amount produced, bought, sold, and
11 otherwise transferred when it comes to prescription
12 opioids?

13 A I would need to look at the testimony.

14 Q. You don't have a view on whether that's
15 accurate or not?

16 A No.

17 Q. Are you aware that the DEA every year
18 sets quotas for how many prescription opioids can be
19 made?

20 A I'm generally aware.

21 Q. And are you aware that they set those
22 quotas based on estimated medical scientific
23 research and industrial needs of the United States?

24 A Generally.

25 Q. Every opioid pill that's manufactured

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1 distributed, or dispensed has to be within that
2 quota, correct, under the law?
3

4 A I'm not that familiar -- I'm not
5 familiar with those laws, so I wouldn't offer an
6 opinion on that.

7 Q. Okay. Let me ask you this then.

8 Do you know if there's ever occasion you
9 can point us to where a manufacturer made opioids
10 that exceeded the permissible quota by the DEA or a
11 distributor shift opioids that exceeded permissible
12 quota of the DEA?

13 A I'm not aware.

14 Q. And let me just for terminology, in this
15 case certain chain pharmacies, CVS, Rite Aid,
16 Walgreens, Walmart have been sued as distributors.
17 So I'm going to include them in my definition of
18 distributors, if you're okay with that, because they
19 supply, in some instances, in some time periods,
20 they supply prescription opioids to their chain
21 stores. Does that make sense? Are you aware of
22 that fact?

23 A I know that.

24 Q. Okay. Did you know that before I told
25 you?

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A No.

Q. Do you understand that the prescription opioid supply by law cannot exceed the DEA quota?

A I'm sorry. Can you just repeat that question?

Q. Of course.

Do you understand, yes or no, that the prescription opioids supplied by law cannot exceed the DEA quota?

A Again, I'm not familiar with the DEA regulations.

Q. Do you understand the DEA has the power to reduce prescription opioids supplied by reducing it's quota?

A I haven't reviewed the DEA regulations.

Q. Okay. And do you know factually that throughout the '90s and the 2000s the DEA continually increased quotas?

A Again, I have not reviewed that.

Q. So you're not offering opinion on whether or not DEA quotas contributed to the opioid supply; is that correct?

Let me ask the question differently.

Are you offering an opinion, yes or no,

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on whether the DEA quotas contributed to the opioid supply?

A Generally I'm offering the opinion that anything that increased the supply was contributing. So to the extent that the DEA did that, and I have not reviewed the regulations, it would be consistent with the opinion that factors that increase the supply are involved and increase to the supplier.

Q. So you haven't looked at the regulations regarding the quotas, correct?

A That's correct.

Q. You haven't looked at the facts regarding the quotas that the DEA was doing, correct?

A That's right.

Q. But you would agree that if the DEA did, in fact, increase the quota, that would increase supply, correct?

A I would need to review the material, but...

Q. Yes, okay. You didn't perform any specific evaluation or analysis in your report or your methodology as to whether the specific amount of opioid harm would have occurred in the absence of

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specific DEA increases to the quota, correct?

A Can you rephrase the question? It's about the DEA?

Q. Yes, it's about the DEA and their quotas. Did you perform an analysis -- as part of your methodology in this case, did you perform an analysis or evaluation of whether the same amount of harm would have occurred in terms of prescription opioids in the absence of the DEA changing quotas year to year?

A No.

Q. Let me turn to another factor, doctors. Am I correct that the only legal way to get prescription opioids is to go to a licensed prescriber?

A Yes.

Q. No matter how many opioids a distributor ships to a pharmacy without a prescription from a doctor, those opioids are supposed to sit on the shelf and not go out to the public, correct?

A I'm sorry. Say that again.

Q. Sure. No matter how many opioids a distributor ships to a given pharmacy, if there's not a prescription from a doctor, those opioids are

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1 supposed to stay in that pharmacy and not go out to
2 the public, correct?

3
4 A That's correct.

5 Q. And you've not identified prescription
6 opioids that the distributor in this case shipped
7 that were dispensed in New York without a valid
8 prescription being written, correct?

9 A Correct.

10 Q. Is there any contribution you can
11 identify that individual distributors made to the
12 supply of prescription opioids available to New York
13 citizens that was not linked to a doctor writing a
14 prescription for those opioids?

15 A Can you repeat?

16 Q. Yes.

17 Is there any contribution you can
18 identify that a specific distributor in this case
19 made to the supply of prescription opioids available
20 to New York citizens that came about in some way
21 other than in connection with a doctor writing a
22 prescription for that opioid?

23 A No.

24 Q. As a result, doctors play a role in
25 determining the supply of prescription opioids,

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correct?

A Yes.

Q. And in evaluating the causes of the opioid crisis, it's important to evaluate the role of doctors who prescribe opioids, correct?

A Yes.

Q. Are you familiar with DEA statements -- I'll ask you about a different set of DEA statements. Also our Congress saying that the overwhelming majority of doctors, more than 99 percent, prescribe opioids to their patients in good faith; are you aware of such statements?

A I'm not familiar with those.

Q. Did you hear -- did you listen to Dr. Lembke yesterday?

A Yes. I listened to some, part of it.

Q. Did you hear her say that there was a wholesale paradigm shift in how doctors prescribed that led to the opioid crisis?

A I didn't hear that part.

Q. Do you agree with that statement?

A Can you say it again?

Q. That there was a paradigm shift in prescribing practices across the medical community

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that led to the opioid crisis?

A My methodology doesn't cover that.

Q. Okay. You distinguish in your report between doctors who are prescribing based on their perception of medical need and something called pill mill doctors, correct?

A Yes.

Q. And have you undertaken any assessment of how much of the prescribing or the supply during the opioid crisis was due to pill mill doctors versus the doctors who are prescribing based on their perception of medical need? Have you tried to allocate that?

A There is a section in my report where I detail some opinions related to that.

Q. Do you actually allocate it? Can you tell us how much of supply was due to pill mill doctors versus doctors prescribing in good faith?

A Not a specific number, no.

Q. Do you agree with me that the overwhelming majority was due to doctors in good faith, or do you know?

A Was due to doctors, yes.

Q. Well, I think it was all due to doctors.

1
2 My question is: Was it due to doctors in good
3 faith? Do you have a view on that, whether the
4 overwhelming majority of supply in New York was a
5 result of doctors acting in good faith versus pill
6 mill doctors?

7 A Yes. I think that the overwhelming
8 majority of prescriptions is due to doctors who were
9 prescribing based on their understanding at the
10 time.

11 Q. And you're aware that doctors increased
12 prescribing levels for prescription opioids starting
13 in the '90s through the 2000s up until 2010,
14 correct?

15 A Yes.

16 Q. You agree that the high volume of opioid
17 prescriptions became the foundation for the overall
18 expansion in the opioid supply and opioid-related
19 harm, correct?

20 A Say that again.

21 Q. You agree that the high volume of opioid
22 prescriptions became the foundation for the overall
23 evaluation -- I'm sorry -- the overall expansion in
24 the opioid supply and opioid-related harm?

25 A Yes.

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1
2 Q. You believe that overprescription helped
3 contribute by doctors helping contribute to the
4 increase in opioid disorder, overdose, and related
5 harms, correct?

6 A Yes.

7 Q. You believe that the expansion of
8 nonmedical use of prescription opioids would not
9 have occurred without that increase in the opioid
10 supply dispensed for medical use, correct?

11 A Yes.

12 Q. In fact, in your publications, you've
13 said that the data are robust in demonstrating that
14 rates of overdoses are proportional to the rates of
15 prescription, correct?

16 A It depends on what time period that
17 we're talking about.

18 Q. You published that in an article in
19 2013, correct?

20 A Yes.

21 Q. Do you stand behind that statement as to
22 the facts as they existed before 2013?

23 A Can you say the sentence again?

24 Q. Yeah. The sentence is: The data are
25 robust, however, in demonstrating the rates of

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overdoses are proportional to the rates of prescriptions.

A Yes.

Q. As part of your methodology in this case did you perform any specific analysis as to whether the opioid crisis would have occurred at all or how much different it would have been in terms of the harm in the absence of doctors increasing their prescribing and thus increasing the supply of prescription opioids?

A By a specific analysis, can you --

Q. Yeah. Did you try to quantify how different it would be if doctors had not increased their prescribing?

A No.

Q. You do agree that doctors play a role in bringing about the opioid crisis?

A Yes.

Q. And you agree that opioid harm would not have occurred at the same level in the absence of doctors increasing their prescribing of prescription opioids?

A Yes.

Q. Opioid supply would not have increased

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1 without doctors playing a role in prescribing of
2 prescription opioids, correct?

3
4 A That's correct.

5 Q. Now, you've talked briefly at the end of
6 your testimony this morning about marketing and how
7 that influenced doctors. There are other factors
8 that have been cited as influencing doctors and
9 their prescribing practices, correct?

10 A That's right.

11 Q. When the State of New York, the entity
12 you represent in this case, makes statements to the
13 medical profession about things like prescription
14 opioids, do you expect them to follow generally
15 accepted practices?

16 A Sorry. Can you say that again?

17 Q. Yes. When the State of New York gives
18 guidance to doctors in New York about prescription
19 opioids, do you expect them to follow generally
20 accepted medical standards?

21 A Yes.

22 Q. Have you undertaken a thorough review of
23 all of the statements that the State of New York
24 made to doctors in New York encouraging them to
25 consider using prescription opioids?

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A No.

MR. SCHMIDT: Let's just look at one example and then we'll move on. May I approach, your Honor?

THE COURT: Yeah, sure.

Normally the way we do it is the court officer is like the liaison between.

MR. SCHMIDT: Okay. Do you want me to ask to approach every time I approach the witness?

THE COURT: Ask me.

MR. SCHMIDT: Okay. I will then.

BY MR. SCHMIDT:

Q. Have you seen this document before which is Defense New York 5260 entitled, "New York's Medical Conduct Program. Pain Management: A guide For Physicians"? Have you seen this document before?

A I may have. I don't recall a specific time. I have may have seen this before. I reviewed a lot of these types of materials in the course of my work.

Q. Okay. It's not on your reliance list. Does that rule out you having seen it?

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2 A It doesn't rule it out. I may have seen
3 it before.

4 MR. SCHMIDT: Let's put it up on the
5 screen, Mr. Reynolds, if we can.

6 MR. REISMAN: Your Honor, I'm going to
7 object on the basis that there's no
8 foundation to use this document right now.
9 This is a hearing about qualifications and
10 methodology, and he is showing documents
11 that --

12 THE COURT: Let me see where it goes.
13 You said there's no foundation?

14 MR. REISMAN: Yes.

15 THE COURT: Well, the witness is brought
16 here by the Plaintiffs, right?

17 MR. REISMAN: Yes.

18 THE COURT: So is foundation really the
19 source of your objection or something else?

20 MR. REISMAN: Well, it's also just --
21 it's beyond the scope of what this hearing is
22 about.

23 THE COURT: What was your last question,
24 please?

25 MR. REISMAN: I think it was: Have you

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seen -- does the fact that it's not on your
reliance list rule it out as something that
you looked at.

THE COURT: Overruled.

Let's see where it goes.

BY MR. SCHMIDT:

Q. Do you see on the first page right in
the center after the title that we've read, there's
the logo for the State of New York and reflecting
that this document is from August 2007? It's got
Governor Spitzer on it. Do you see that?

A Yes.

Q. If we look at the second page of this
document, I just want to highlight two sentences in
this document.

First of all, on the left hand under
introduction, do you see the third paragraph? It
helps to look on the screen. We're going to
highlight it on the screen just to make it easier
for you to find.

It says "The board encourages and
expects physicians to view effective pain management
as part of quality medical practice for all patients
with pain, acute or chronic, including pain as a

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1
2 result of terminal illness." Do you see that
3 language?

4 A I do.

5 Q. And then I want to look at the language
6 under controlled substances. "The board recognizes
7 that controlled substances, including opioid
8 analgesics, are often essential in the treatment of
9 acute and chronic pain, both malignant and
10 nonmalignant." Do you see that language?

11 A Yes.

12 Q. I'll ask you just two questions about
13 that language. First of all, yes or no, do you
14 agree with that statement about opioid analgesics
15 being essential or often essential in the treatment
16 of acute and chronic pain, both malignant and
17 non-malignant, or do you have a view on that?

18 A I don't agree with that statement.

19 Q. Did you conduct any kind of analysis of
20 whether documents like this, whether the doctors or
21 similar documents to New York residents as patients
22 from the State of New York, whether they had a
23 specific impact on physician prescribing decisions
24 and the levels of supply in the State of New York?

25 A No.

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1 Q. Did you conduct any evaluation or
2 analysis as to whether the same amount of harm would
3 have occurred in the State of New York if the State
4 of New York itself were not telling doctors
5 statements like this that you disagree with about
6 prescription opioids? Did you conduct that type of
7 analysis?
8

9 A No.

10 Q. That's my foundation, your Honor. I'll
11 move on.

12 THE COURT: It's a 2008 document, yes?

13 MR. SCHMIDT: Yes. And I'm happy to
14 show more from an earlier time period, but in
15 the interest of time, I'll move on to my next
16 topic, unless your Honor wants to hear more
17 on this topic.

18 THE COURT: No, I'm fine.

19 MR. SCHMIDT: I assume the answer will
20 always be no more on any given topic.

21 THE COURT: I'm fine.

22 BY MR. SCHMIDT:

23 Q. Do you agree that insurance company
24 decisions about whether to cover prescription
25 opioids were given favorable formulary treatment of

1
2 prescription opioids, and correspondingly whether
3 they cover nonopioid treatments for pain were given
4 favorable formulary coverage, that those could have
5 an impact on prescription opioid suppliers?

6 A Yes.

7 Q. And your report doesn't evaluate
8 insurance formulary decisions, correct?

9 A Incorrect.

10 Q. Okay. Have you conducted an analysis
11 that let's you say this is the amount of harm that
12 would have occurred but for the fact that insurance
13 plans of any sort gave favorable coverage,
14 prescription opioids and less favorable coverage to
15 alternative pain treatments?

16 A Can you say a specific quantity, a
17 number?

18 Q. Yes.

19 A No.

20 Q. Okay. You don't mention New York
21 Medicaid once in your report, correct?

22 A Not as far as I remember.

23 Q. Do you understand that New York Medicaid
24 has discretion in terms of whether to put an opioid
25 treatment or a nonopioid treatment on its preferred

1
2 versus nonpreferred list?

3 A I'm generally familiar with that.

4 Q. Do you understand that if it's on the
5 preferred list, it doesn't require prior
6 authorization from a doctor?

7 A Yes.

8 Q. And do you understand that as a result,
9 medications on the preferred drug list are used more
10 by New York Medicaid recipients?

11 A I'm not aware of an epidemiological
12 study of that.

13 Q. Are you aware of that being a fact?
14 Have you seen testimony from state witnesses in this
15 case acknowledging that fact?

16 A I haven't seen that testimony.

17 Q. We heard yesterday, and tell me if you
18 were here for this part of Dr. Lembke yesterday,
19 that New York Medicaid patients are more likely to
20 be prescribed prescription opioids.

21 Do you take issue with that fact, that
22 New York Medicaid residents are more likely than
23 other New York residents to be prescribed
24 prescription opioids?

25 A I haven't looked at the studies.

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1
2 Q. That's not something that you've
3 evaluated?

4 A That's not something I evaluated.

5 Q. We heard yesterday that New York
6 patients are more likely to experience harm from
7 prescription opioids than non New York Medicaid
8 patients. Do you take issue with that?

9 A I'm sorry. Can you say that again?

10 Q. Yeah, of course. We heard yesterday
11 that New York Medicaid patients are more likely to
12 experience harm from prescription opioids than non
13 Medicaid patients. Do you take issue with that
14 proposition?

15 A Again, I would need to look at the data.

16 Q. That's not something you evaluated?

17 A That's not something I evaluated.

18 Q. And so let me kind of come back and ask
19 the question more broadly. Am I correct that as
20 part of your methodology in this case, you did not
21 evaluate New York Medicaid formulary and other
22 coverage decisions regarding prescription opioids?

23 A I evaluated other coverage decisions,
24 but not New York Medicaid.

25 Q. Do you know, for example, that in just a

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1
2 five-year period, between 2012 and 2017, New York
3 Medicaid paid for nearly 600 million opioid pills in
4 the State of New York?

5 A I have not evaluated that.

6 Q. You've not conducted any kind of
7 analysis in your methodology where you say if New
8 York Medicaid would have made different decisions in
9 terms of how they cover prescription opioids and
10 reimburse prescription opioids, would we have the
11 same level of harm in New York from prescription
12 opioids, correct?

13 A Correct.

14 Q. You've not analyzed whether if New York
15 Medicaid made different decisions about coverage of
16 prescription opioids, we would have a different
17 level of supply of prescription opioids in New York
18 State, correct?

19 A Correct.

20 Q. I asked you earlier about pill mill
21 doctors. I think you defined them in your report
22 has high-volume prescribers who inappropriately
23 prescribe prescription opioids for profit.

24 Does that sound like a reasonable
25 definition?

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A Yes.

Q. And do you agree that they have contributed to the increase in opioid use disorder, overdose, and related harms?

A Yes.

Q. Do you agree that pill mill doctors helped increase the supply of prescription opioids?

A Yes.

Q. Do you understand that over time New York State has licensed pill mill doctors and has made the decision to reregister pill mill doctors and has failed to investigate specific pill mill doctors?

A I haven't, I haven't looked at that material.

Q. So you've done no analysis of whether the level of harm from prescription opioids would be different but for the licensing and reregistration and failure to investigate decisions made by the State of New York regarding pill mill doctors?

MR. REISMAN: Objection, lack of foundation.

THE COURT: I'll call it a compound question. Call it objection to form, and

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I'll sustain it.

MR. REISMAN: Okay. Objection to form.

THE COURT: Objection to form sustained.

Rephrase it.

MR. SCHMIDT: Thanks, your Honor.

BY MR. SCHMIDT:

Q. Have you done any analysis of whether New York State would have made different licensing decisions regarding pill mill doctors --

THE COURT: Yes or no.

Q. -- that would have led to a different level of harm from the opioid crisis? Yes or no.

MR. REISMAN: Objection to form.

THE COURT: Okay. There are two form objections, right? Assuming a fact not in evidence and a compound question. It probably hits -- it probably rings the bell on both of them.

MR. SCHMIDT: I don't think so, your Honor. There's ample facts in evidence about New York State's failure, including in prosecutor documents, failure to investigate pill mill doctors.

THE COURT: You mean evidence in this

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courtroom or evidence in the submissions?

MR. SCHMIDT: That's been generated in discovery in this case, and I'm happy to put that on the record right now.

THE COURT: No. I'll take your word for it.

MR. SCHMIDT: Okay.

THE COURT: By the way, Doctor, can you handle the question?

THE WITNESS: Can it be repeated?

THE COURT: I'm going to have the stenographer read it back to you. Then I'm going to ask you, can you handle the question. You will answer me and then I will direct you.

MR. SCHMIDT: If it's easier, I can try to simplify it.

THE COURT: Simplify it.

BY MR. SCHMIDT:

Q. Have you done an analysis of whether we'd have the same level of harm from the opioid crisis had New York State made different licensing decisions regarding pill mill doctors?

A No.

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THE COURT: Find a place to break for lunch.

MR. SCHMIDT: This is probably as good a place as any.

THE COURT: See everybody at 2:00. Thank you.

(WHEREUPON, after a luncheon recess, the following was had:)

THE CLERK: Come to order. Part 48 is now in session.

THE COURT: Doctor, you can resume the stand. Please be seated, everybody.

THE CLERK: Doctor, I remind you you're still under oath.

THE WITNESS: Thank you.

THE COURT: You may proceed. Thank you.

MR. SCHMIDT: Thank you, your Honor.

CROSS EXAMINATION CONTINUED

BY MR. SCHMIDT:

Q. Doctor, thanks for continuing with us.

I want to pick up now on one last set of topics on the supply question. I want to talk with you about distributors as I opined about earlier, including those chain pharmacies.

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1
2 Tell me if I'm wrong, we obviously have
3 the transcript, am I correct that you did not
4 discuss distributors as a category during your
5 direct examination?

6 A I'm sorry, say the question again.

7 Q. Yeah. You had no discussion,
8 specifically about distributors as a category of
9 entities in your direct examination, correct?

10 A I'm sure -- if you have the transcript,
11 I'm sure that's correct.

12 Q. You didn't mention any distributors or
13 chain pharmacies by name, correct?

14 A Correct.

15 Q. You didn't talk about the specific role
16 of distributors or their obligations with respect to
17 controlled substances in your direct, correct?

18 A We talked about supplies but not
19 specific distributors.

20 Q. Right. You didn't talk about
21 distributors' role in setting supply and meeting
22 their obligations at that point, correct?

23 A Sure. Correct.

24 Q. As part of your methodology, you did not
25 estimate the appropriate level of opioid supply in

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New York State; is that right?

A That's right.

Q. You didn't do an analysis, say, looking at medical conditions that opioids are used for and how many people have those conditions in New York; therefore, how many opioids you might want to expect to see, correct?

A I did not do that analysis.

Q. You didn't analyze whether changes in opioid overdose rates track with changes in any individual distributor's distribution levels over time, correct?

A No.

Q. "No," being I'm correct in saying that?

A You are correct.

Q. Okay. As part of your methodology did you evaluate specific distributors in your report?

A No.

Q. For example, your report doesn't mention McKesson, Cardinal, ABDC, the chain pharmacies at all, correct?

A No, I don't think so.

Q. "No," it doesn't mention them?

A Correct.

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1
2 Q. Okay. Your article -- your report, and
3 I think you talked about this in your direct exam,
4 cites nearly 200 articles that you relied on in
5 forming your opinions.

6 Do you recall giving that testimony
7 earlier today?

8 A Yes.

9 Q. That epidemiological literature that you
10 cited does not specifically discuss McKesson's
11 conduct or programs, Cardinal's, ABDC's or the chain
12 pharmacies, correct?

13 A As a whole, yes; but specifically, no.

14 Q. It doesn't focus on whether anyone of
15 those entities met their obligations or their level
16 of contribution to supply or anything like that,
17 correct?

18 A Correct.

19 Q. In the report you originally were served
20 in this case doesn't cite any document from any
21 distributor in this case, correct?

22 A Correct.

23 Q. In fact, when we talked at your
24 deposition you weren't sure if you'd ever seen a
25 document created by a McKesson employee, a Cardinal

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1
2 employee, an ABDC employee or chain pharmacy
3 employee, correct?

4 A Correct.

5 Q. As part of your methodology, am I
6 correct that you did not assess any individual
7 distributor's contribution to opioid supply relative
8 to other distributors?

9 A That's correct.

10 Q. You didn't consider the specific volume
11 of prescription opioids that any one distributor
12 brought into New York State or Nassau County or
13 Suffolk County; is that correct?

14 A I'm sorry, can you repeat the question?

15 Q. Yeah, of course.

16 You didn't consider the specific volume
17 of prescription opioids that any one distributor
18 brought into New York State or Nassau County or
19 Suffolk County, correct?

20 A Not any one distributor, no.

21 Q. You didn't know, at least at the time of
22 your deposition, how much they actually brought into
23 New York for Nassau or Suffolk, correct?

24 A That's right.

25 Q. And you didn't analyze how much they

1 shipped to the specific pharmacies either; is that
2 correct?
3

4 A That's correct.

5 Q. Am I right that there's no pharmacy
6 you've been able to identify or group of pharmacies
7 you've been able to identify in New York State where
8 a distributor in this case in your view shipped too
9 many prescription opioids?

10 A That's right.

11 Q. Am I correct you did not even study
12 individual pharmacies in terms of knowing which
13 distributors supplied which pharmacies?

14 A That's right.

15 Q. Am I correct that you can't identify any
16 times when a pharmacy that was a customer of one of
17 the distributors in this case or supplied by one of
18 the distributors in this case filled an improper
19 prescription or had a diverted prescription?

20 A I'm sorry, can you repeat the question?

21 Q. Sure. Am I correct that you cannot
22 identify any pharmacy or any volume of pharmacies in
23 New York State that were supplied by distributor
24 Defendant in this case, that filled an improper
25 prescription or had a diverted prescription?

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1
2 A Overall that's documented in the
3 literature, but not a specific pharmacy. But in
4 terms of groups of pharmacies that I believe is in
5 the report.

6 Q. Have you attempted to link groups of
7 pharmacies to specific distributors in this case,
8 groups of New York pharmacies?

9 A No.

10 Q. Am I correct that you could not identify
11 for us any pharmacy or any group of pharmacies that
12 were acting improperly in New York State that
13 stopped acting improperly or went out of business
14 because one of the distributes in this case cut them
15 off?

16 A No.

17 Q. "No," you can't identify that?

18 A That's correct.

19 Q. Okay. Have you been able to identify
20 any doctor who was forced or prescriber who was
21 forced to stop writing improper opioid prescriptions
22 because one of the distributors in this case cut off
23 the pharmacy that those prescriptions were being
24 filled out of?

25 A A specific doctor?

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Q. Yes.

A No.

Q. Have you done any analysis of whether any of the distributor Defendants, take McKesson, if they had decided not to ship prescription opioids and another distributor had stepped in, whether the level of opioid harm would have been any different in the State of New York?

A I'm sorry, can you breakdown --

Q. Sure.

A Okay. So one distributor stops --

Q. Yes, and another distributor steps in, would the level of opioid harm had been any different?

A No.

Q. You haven't done that analysis?

A No.

Q. And you talked about marketing at the end of your opinions, I just want to ask you a couple of questions on marketing.

You don't know of a single time when McKesson, Cardinal, ABDC, one of the chain pharmacies gave marketing materials to a doctor in New York State, correct?

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A No.

Q. "No," you don't no that?

A I don't know that.

Q. You don't know of a single time when McKesson, Cardinal, ABDC, a chain pharmacy prepared specific marketing materials for doctors or patients, correct?

A That's correct.

Q. And the literature you've seen in terms of talking about marketing and points to entities other than McKesson, Cardinal, ABDC and chain pharmacies as conducting marketing to physicians regarding prescription opioids; is that correct?

A That's right.

Q. Do you agree that the opioid crisis was caused by multiple different factors?

A Yes.

Q. Would you agree that there are multiple interrelated and deeply rooted social and economic determinants of the U.S. opioid overdose crisis?

A Among others, yes.

Q. And in your work you've not attempted to assign percentages of responsibility for the opioid crisis in New York to Cardinal or McKesson or ABDC

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or the chain pharmacies, correct?

A That's correct.

Q. Or to the manufacturers, correct, as individual entities?

A That's right.

Q. What is correct -- well, is it correct that you would -- strike that.

Would you agree with me that the actions of distributors alone are not sufficient to bring about the opioid crisis?

A I would agree with that.

Q. The actions of manufacturers alone were not sufficient to bring about the opioid crisis?

A Yes.

Q. Am I correct that you cannot even answer the question whether you would fault McKesson?

A I -- that's incorrect.

Q. Okay. Do you remember giving a deposition in this case?

A Yes.

MR. SCHMIDT: Could we pull up page 86 of the New York deposition.

Q. You were under oath in that deposition, correct?

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A Yes.

MR. SCHMIDT: And can we go to line 11,
if we can put that up on the screen, Mr.
Reynolds. It's going to be 86.

So you can actually take that down for a
second, Mr. Reynolds.

Q. And if you look at page 86, just before
on line 5; do you see where I'm referencing?

A Um-hm.

Q. I say: "Okay." And you say, "So to the
extent that McKesson was involved in increasing
supply of opioids, it's likely more than not."

Do you see that testimony?

A Yes.

Q. And then this is the part I wanted to
ask you about, this is the part we have up on the
screen: "QUESTION: Do you fault McKesson?

"ANSWER: I can't answer that?"

Did I read that correctly as your
testimony from our deposition in this case?

A Yes.

Q. Would the same statement apply to
Cardinal, ABDC, and the chain pharmacies, that you
can't answer whether you fault them for opioid harm;

yes or no?

A I think they've more than likely contributed to harms, but in terms of percentage fault, I don't have a -- that's what I was interpreting that question to mean.

Q. Okay. You published nearly 275 peer review articles, I think you talked about that on direct?

A Yes.

Q. 20 of them address opioids specifically?

A Yes.

Q. Some of them address causes of the opioid crisis?

A Yes.

Q. You follow generally accepted methodologies in your publications?

A Yes.

Q. None of them refer to McKesson as a cause of the opioid crisis, correct?

A Correct.

Q. None of them refer to ABDC or Cardinal or the chain pharmacies as a cause of the opioid crisis, correct?

A That's right.

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1
2 Q. None of them refer to any of the
3 defendants in this case as a cause of the opioid
4 crisis, correct?

5 A No specific company, but generally
6 speaking about different, different parts of the
7 distribution and supply of opioids, yes.

8 Q. Is there a publication you can point us
9 to where you say that publication distributors as a
10 class caused the opioid crisis?

11 A Not back then, no.

12 Q. I'd like to now shift from supply to the
13 gateway theory and ask you some questions about the
14 gateway theory and your opinion that prescription
15 opioid use is related to subsequent heroin and
16 illegal fentanyl use, and we talked earlier about
17 the difference between association and causation; do
18 you recall that?

19 A Yes.

20 Q. You rely on articles talking about
21 whether there is an association between heroin use
22 and earlier prescription opioid use, not medical,
23 prescription opioid use, correct?

24 A That's correct.

25 Q. Have you published any articles where

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2 you say there's established cause between nonmedical
3 prescription opioid use and later heroin or illegal
4 Fentanyl use?

5	A	Not to my knowledge.
---	---	----------------------

6 Q. You agree that there is a heroin problem
7 before the opioid crisis?

8 A I'm sorry, say that again.

9 Q. Was there a heroin problem before the
10 opioid crisis?

11 A There was heroin use before the opioid
12 crisis.

13	Q. Was there a problem?
----	-------------------------

14	A	All heroin use is a problem so.
----	---	---------------------------------

15 Q. Okay. And are you aware that there was
16 specifically a heroin problem in New York State
17 before the opioid crisis?

18 A There were -- there was, yes.

19 Q. Have you studied the degree in which the
20 heroin problem existed in Suffolk County or Nassau
21 County before the opioid crisis?

22 A I have not.

23 Q. Do you agree with me that even today
24 there are heroin users who did not start using
25 prescription opioid or did not use prescription

opioid before using heroin?

A Yes.

Q. Have you attempted to quantify how many, how many heroin users over the past ten years would have used heroin even if the supply of prescription opioids would not have increased in the '90s and 2000s; do you have a number for that?

A I believe we can point to the literature to give us general guidelines on that.

Q. Do you know what the number is? How many people would still use heroin today even if there had not been an increase in prescription opioid slide in the '90s to 2000s; can you ballpark what that number is for us in your view?

A So if you could just go a little slower.

Q. Of course, I'm sorry.

A How many people would be using heroin now --

Q. But for the increase in prescription opioid supply in the '90s and 2000s; do you know?

A I think that if we looked at the literature, given the magnitude of the association, it would probably be kind of taking the inverse of the proportion we use prescription opioids before

heroin, it would be four to five times lower.

Q. Okay. Do you know what the number is?

A The specific number would be using heroin now?

Q. Yes.

A It would be whatever it was similar to in the early '90s.

Q. Is that a calculation you performed?

A I haven't performed that calculation. I'm just expressing the opinion now.

Q. In slide 16 of your analysis you talked and in your report you talk about 16 studies that you rely on evaluating whether there's an association between nonmedical use of prescription opioids and later use of heroin, correct?

A Yes.

Q. And to be clear, those studies are focused on nonmedical use of prescription opioids, correct?

A There are several that, that describe connections between medical use of opioid as well.

MR. SCHMIDT: Okay. Can we pull up slide 16, is that possible, Mr. Reynolds, from Plaintiffs' slide?

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1
2 Q. And while we're doing that, are you
3 aware that there have been changes in the heroin
4 market since the 1990s in terms of price,
5 availability, supply.

6 A Yes.

7 Q. Okay. I'll come back to that.

8 Could we look at slide -- I think I've
9 got the wrong number. It's actually slide 20.
10 Yeah, slide 20.

11 Do you see where you talk about the 16
12 studies here?

13 A Yes.

14 Q. And do you see where you use the term
15 individuals who use prescription opioids
16 nonmedically; do you see that?

17 A Yes.

18 Q. And you say the same thing in your
19 report, correct, you refer to nonmedical use?

20 A Yes.

21 Q. And nonmedical use is opioid misuse,
22 correct?

23 A Generally speaking.

24 Q. You're not aware of studies that look at
25 whether people who use prescription opioids

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medically have higher than average levels of heroin use, correct?

A Incorrect.

MR. SCHMIDT: Okay. Let's take a look at your testimony, please. Page 323, line 19, to 324, line 5. Mr. Reynolds, are you able to put that testimony up on the screen, please.

THE COURT: It's up.

Q. If we go from page 323, line 19, to 324, line 5, let me ask my question differently.

"Have you seen any studies showing that patients who only use prescription opioids medically have higher rates of injecting --" and it says sorting, I think it was snorting -- "snorting heroin; yes or no?"

"ANSWER: I don't know of an epidemiological study to strike and answer that question."

Did I read that correctly and do you recall being asked that question and giving that answer?

A Yes.

Q. Your own research results do not support

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legitimate opioid prescription use by itself as a major distributor chronic opioid misuse, correct?

A Can you state that again.

Q. Of course, yeah.

Your own research results do not support legitimate opioid prescription use by itself as a major contributor to chronic opioid misuse, true? Do you agree with that statement?

A I would need to go back to -- is there a specific paper that you're referring to?

Q. There is, but can you tell me, just without seeing the paper, whether you agree with that statement?

A It would depend on the study. I wouldn't say that that's an across the board statement.

Q. Do you still have in front of you the paper that you published in 2015 that the Plaintiffs' counsel showed you?

A Yes.

Q. Demonstrative 56, you're the fourth author or this; do you see this?

A Yes.

Q. I think you described this as a cohort

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1 study where you attempted to follow a generally
2 accepted method, reasonably generally accepted
3 methods in this paper?
4

5 A Yes.

6 Q. I think you said on direct that you were
7 involved in the data analysis, interpreting the data
8 and writing the report?

9 A Yes.

10 Q. And did I hear you say that you
11 controlled further risk factors in this study?

12 A Yes.

13 Q. Okay. Let's look at page 7 of the
14 study, please, and if we can put this up on the
15 board, it's demonstrative 56, page 7.

16 Do you see in the bottom right-hand
17 paragraph, the one that continues over, if we could
18 make that bigger, do you see that you talk about
19 limitations of this study?

20 A Yes.

21 Q. Now I want to focus on the second
22 limitation. The second. (READING:) The data do
23 not contain information on unmeasured confounding
24 factors, such as family history or mental illness --
25 and then it goes on to say -- although it is likely

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that by 12th grade drug use history and drug attitudes serve as proximate causes for these more distal influences on drug misuse.

Is that an accurate statement that the data do not contain information on unmeasured confounding factors, such as family history or mental illness?

A That's an accurate statement.

Q. Now move, if you would, at the sentence that begins at the bottom of the first column on this page, please and carries over to the second column, and this is that language I was reading you just a few moments ago.

And, Mr. Reynolds, we can actually just call up the last line of that, if that makes it easier. It's just the word these, because it carries over.

Thank you for that.

You write (READING:) These results do not support legitimate opioid prescription use by itself as a major contributor to chronic opioid misuse, at least not by 23.

Did I read that correctly?

A Yes.

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1
2 Q. You stand by that statement within the
3 statement?

4 A Yes.

5 Q. And is that a generally accepted
6 principle in your field, what you wrote in this
7 paper?

8 A I don't think it's a principle.

9 Q. Is it a generally accepted statement?

10 A I think it's -- no, I think that this is
11 a sentence that describes the results of this paper,
12 and I can expand on the results if you would like me
13 to.

14 Q. Can you point me to -- actually, let me
15 ask you about one other study that you talked about
16 on direct.

17 Do you remember talking about that
18 McCabe study that you did not cite in your report
19 but that we talked about at your deposition?

20 A Yes.

21 Q. That is demonstrative 54. If you can go
22 ahead and put that up on the screen. It was showed
23 on slide 19.

24 Did you testify -- I want to be sure I
25 understood what you said about this study -- did you

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say that this study did not speak to whether medical use without nonmedical use is linked to higher rates of heroin use or other drug use?

A I'm sorry, can you say that again?

Q. Sure. Let me ask it more simply.

I thought I heard you say this and tell me if I heard it right.

Does this study say, speak to whether if someone uses opioids medically and not nonmedically they have later higher rates of other drug use; does this study speak to that question?

A Later higher rates of -- I'm sorry, what outcome?

Q. Other drug use.

A No.

Q. It does not speak to that?

A No, not other drug use. They look at substance use disorders, symptoms at age 35.

Q. Including substance use symptoms from other drugs, right?

A Yes.

Q. Let's look specifically at what I'm asking about. Can we go to page 5, please. The second to last full paragraph on the page,

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adolescents.

By the way, is this study performed, in your view, using generally accepted methods?

A Yes.

Q. It says: "Adolescents who indicated medical use without a history of --" and I'm going to fill in the acronyms, tell me if I get it wrong. So let's start again.

"Adolescents who indicated medical use without a history of nonmedical use of prescription opioids did not differ from adolescents with no history of medical use of prescription opioids or nonmedical use of prescription opioids in the odds of alcohol use disorder, cannabis use disorder or other drug use disorder."

Did I read that correctly? Fill in any acronyms.

A Generally.

Q. And do you agree with that finding in this study, is that a reasonable interpretation of the data in the study; yes or no?

A Um, I think that I would have written it differently, so no.

Q. Is it wrong in your view?

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A It's not wrong.

Q. Can you point me to a contrary study showing individuals who use prescription opioids only medically have higher rates of heroin use?

A Sorry, say that again.

Q. Can you point me to a contrary cite showing individuals -- actually, no. I think I just asked you this question, so I'm going to move on.

I've asked you now about medical use prescription opioids, so I want to move over to nonmedical use of prescription opioids. Those 16 studies that you cited.

Do you consider each of those studies to be reliable when conducted using generally accepted methods?

A Yes.

Q. Going back to that distinction we drew between causation and association, am I accurate that none of those studies make the step of going beyond association to causation?

A No one study alone, no.

Q. None of them collectively, correct?

A Collectively, I think that's up to the epidemiologist.

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1 Q. Does anyone of those studies say,
2 looking at our study and all other studies, we're
3 now willing to conclude causation?
4

5 A Not those words.

6 Q. Do any of them go beyond association?

7 A I think they generally accept the well-
8 accepted principle that prescription opioid use is a
9 risk factor for heroin use.

10 Q. Do they go beyond association; just yes
11 or no?

12 A Um, I would say yes.

13 Q. Okay. Well, let's look at what they say
14 now.

15 MR. SCHMIDT: May I approach, your
16 Honor.

17 THE COURT: Yes.

18 Q. I'm going to give you two things. One
19 is a demonstrative that I prepared, and I don't
20 think that you need to look at the study, but if you
21 would like to look at the study, I've given you a
22 set of the studies on this demonstrative --

23 A Thank you.

24 Q. -- and they're tabbed.

25 The demonstrative is four of the 16

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1 studies, you cite language from the studies. If you
2 can put it up on the screen, Demonstrative Exhibit
3 1, and I think we were using letters, so I'll mark
4 this as Defendant's Exhibit A -- I guess I'll mark
5 it as Defendant's Exhibit B, Exhibit A would be the
6 New York document encouraging opioid use that we
7 looked at earlier.

8
9 Do you recognize these four studies as
10 four of the 16 studies you looked at?

11 A Yes.

12 Q. And just very quickly (READING:)

13 (Khosla) 2011. Temporality and causal
14 associations could not be determined.

15 (Becker) 2008. While we were able to
16 describe associations, we are not able to ascribe
17 causality.

18 (Grau) 2007. A second limitation is the
19 cross-sectional nature of this study, which
20 precludes the possibility of establishing causal
21 relationships.

22 (Havens) 2009. Causal inferences could
23 not be made.

24 Did I read those excerpts right?

25 A Yes.

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1
2 Q. Do you agree with those statements as
3 made in the context of those studies; yes or no?

4 A Yes.

5 Q. And are you aware of any study that goes
6 farther and says we do find causation, we do find
7 more than an association?

8 A I think if you look at the language of
9 the discussion section, you know, limitations of the
10 studies aside, I think there is generally accepted
11 language that prescription opioid use is a risk
12 factor for heroin use.

13 Q. It's important to consider the
14 limitations, right?

15 A Yes.

16 Q. Do you know of any study that actually
17 says we believe there is causation between earlier
18 nonmedical prescription opioid use and later heroin
19 use, where it comes to a specific conclusion, it
20 goes beyond association and concludes causation?

21 A No.

22 Q. Can you point me to any study that
23 states there's general acceptance that nonmedical
24 prescription opioid use causes heroin use or illegal
25 fentanyl use?

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1
2 A I would need to go back to the studies.
3 I mean, off the top of my head, I don't have
4 specific sentences.

5 Q. Is there one you can point me to from
6 your work; just yes or no?

7 A Not off the top of my head.

8 MR. SCHMIDT: Let me show you one other
9 study you looked at. I'll mark this -- if I
10 may approach -- Defendant's Exhibit C.

11 THE COURT: Yes.

12 Q. Do you recognize this as a 2016 New
13 England Journal of Medicine, that's one of your 16
14 studies that you cite?

15 A Yes.

16 Q. This one, the lead author is Compton,
17 and if you look at the heading it's actually a
18 review article, correct?

19 A Yes.

20 Q. It's reviewing the literature that
21 existed at the time of this publication.

22 A Yes.

23 Q. Are you aware that it reviews 14 of the
24 16 studies that you cite in your report?

25 A Yes.

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1
2 Q. If we look at page 3 of this document
3 there's a heading that says: Heroin Use Among
4 People Who Use Prescription Opioids Nonmedically; do
5 you see that?

6 A Yes.

7 Q. Then a little further down, or actually
8 right below that, I'm sorry, it says: "Studies that
9 address the patterns of heroin use in nonmedical
10 users of prescription opioids are mostly
11 observational and descriptive; i.e.,
12 nonexperimental. Thus, conclusions about cause and
13 effect are uncertain.

14 Yet, certain consistent findings of a
15 positive association between nonmedical use of
16 prescription opioids and heroin use are highly
17 suggestive and plausible, given the common
18 pharmacologic principles described above?"

19 Did I read that correctly?

20 A Yes, you did.

21 Q. I want to point you to their later
22 conclusion and ask you about that. Can you go to
23 the fifth page of this article, please. And right
24 before the heading on the right, down at the bottom
25 of this page, if we could pull out the -- yeah, it

Frye Hearing - Dr. Keyes

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1
2 says: "Taken in total, the available data suggests
3 that nonmedical prescription opioid use is neither
4 necessary nor sufficient for the initiation of
5 heroin use and that other factors are contributing
6 to the increase in the rate of heroin use and
7 related mortality."

8 Did I read that correctly?

9 A You did.

10 Q. Do you agree with that; yes or no?

11 A Yes.

12 Q. Is that a generally accepted view, in
13 your opinion?

14 A Yes, absolutely.

15 Q. And "necessary" means all cases of the
16 outcome have a risk factor, correct?

17 A That's right.

18 Q. "Sufficient" means by itself it can
19 bring it about, correct?

20 A That's right.

21 Q. We talked earlier about one of the other
22 factors or some of the other factors: the price of
23 heroin, the availability of heroin, the purity of
24 heroin; do you recall us touching on that?

25 A Yes.

Frye Hearing - Dr. Keyes

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1 Q. If we just stay with Compton,
2 Defendant's Exhibit C. C, as in Compton.
3

4 The first full paragraph on this page 5,
5 just go further on the page. States (READING): A
6 key factor underlying the recent increases in rates
7 of heroin use and overdose may be the low cost and
8 high purity of heroin.

9 Do you recognize -- do you agree with
10 that statement?

11 A Yes.

12 Q. And it goes on to detail that the price
13 of heroin has dropped from 2,690 per gram in 1982 to
14 as low as \$465 in 2012; do you see that?

15 A Yes.

16 Q. And it cites a recent study showed that
17 each hundred-dollar decrease in the price per gram
18 of heroin resulted in a 2.9 percent increase in the
19 number of hospitalizations for heroin use; do you
20 see that?

21 A Yes.

22 Q. Do you take any issue with that data
23 showing that as the price comes down by \$100, for
24 every \$100 there's a 2.9 percent increase in
25 hospitalizations?

Frye Hearing - Dr. Keyes

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1
2 A Availability and price are huge drivers
3 of drug use, yes.

4 Q. Am I correct that you conducted no
5 specific analysis of the impact of heroin price on
6 the number of people who have used heroin over the
7 past several decades?

8 A I'm sorry, say that again.

9 Q. Sure.
10 Did you conduct any specific analysis
11 looking at changes in heroin price and how that
12 impacted harm from heroin over the past couple
13 decades?

14 A Aside from just reviewing the
15 literature?

16 Q. Right. You didn't do any independent
17 analysis?

18 A No.

19 Q. Did you do any analysis to say if there
20 had not been changes in heroin price, here's how the
21 harms from at least illegal heroin and illegal
22 Fentanyl use would have been different?

23 A No.

24 Q. The sentence we looked at also talks
25 about purity in the first sentence.

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Are you aware of law enforcement findings that even as the price has gone down for heroin in New York, the purity of the product has increased in the New York region?

A I'm generally familiar with that literature.

Q. And are you aware of the idea that as it becomes more pure it can be snorted -- for lack of a better, more scientific term -- instead of being injected, it allows for a different method of administration? Maybe that's the more scientific way of saying it.

A Sure. Yes, I'm generally aware of that.

Q. And when that different method of administration is available are you aware of findings that more people are likely to use it because it doesn't have the stigma of needles?

A Yes.

Q. Am I correct that you've done no analysis specifically looking at changes in heroin purity in the New York market and the impact that's had on the harms in heroin use in the State of New York?

A No -- you are correct.

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1
2 Q. You've not evaluated whether if the
3 changes in heroin purity occurred -- had not
4 occurred, I'm sorry -- whether there were -- let me
5 try again.

6 You've not evaluated whether if there
7 were no changes in heroin purity in the New York
8 market the level of harm from heroin would have been
9 different?

10 A I think generally that's what that paper
11 is showing that, that we would predict there would
12 be less harm from heroin.

13 Q. Have you quantified how much less?

14 A No.

15 Q. Between 0 and 100; do you know?

16 A No.

17 Q. And 0 and 100 percent, you don't know if
18 it's 0 percent or -- I guess you said it would be
19 different, between 1 and 100 percent, do you know
20 where the harm would fall?

21 A No.

22 Q. Could be 100 percent different, could be
23 1 percent different, you don't know?

24 A I don't know.

25 Q. You talk about, and I think you talked

Frye Hearing - Dr. Keyes

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1
2 about it just now, but I want to make sure I have
3 it. You talk about in your report something called
4 availability theory?

5 A Yes.

6 Q. I think that's an idea you alluded to a
7 moment ago that one driver of harm is the
8 availability of a product, correct?

9 A That's correct.

10 Q. And you're aware of findings that heroin
11 availability has increased over the last several
12 decades?

13 A Yes.

14 Q. Are you aware of law enforcement
15 findings that Mexican cartels have specifically
16 increased both the amount of heroin poppies that
17 they're growing and the amount that they're
18 importing into markets like New York?

19 A Yes, I'm aware of those.

20 Q. Am I correct that you did not specific
21 analysis of the impact of heroin availability on the
22 harm from heroin usage?

23 A I'm sorry, say -- heroin availability?

24 Q. Sure, let me ask it a little
25 differently.

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I was asking about greater manufacturing of heroin, greater distribution of heroin by illegal drug cartels.

Did you conduct any analysis that would let you say this is how much different heroin harm there would be if they had not increased manufacturing and distribution?

A No.

Q. You don't know whether it's between 100 percent different, 1 percent different or something in between?

A I'm not aware of an analysis that's quantified that.

Q. And that's not something you've done, right?

A No.

Q. Let's -- let me ask you one more question on this Compton article and then we can leave it.

If you turn to page 7 of the article, please.

If we look on the right-hand side, down at the bottom, please, in the last paragraph.

Do you see where it says:

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1
2 "Alternatively, heroin market forces, including
3 increased accessibility, reduced price and high
4 purity of heroin appear to be the major drivers of
5 the recent increases in rates of heroin use."

6 Do you see that?

7 A There was -- you didn't read it
8 correctly.

9 Q. Oh, then let me reread it. I didn't
10 mean to read it incorrectly. That's my garble.

11 Do you see where it states:

12 "Alternatively, heroin market forces, including
13 increased accessibility, reduced price and high
14 purity of heroin appear to be major drivers of the
15 recent increases in rates of heroin use."?

16 A That's right.

17 Q. Okay. Do you agree with that statement;
18 yes or no?

19 A Yes.

20 Q. And is that a generally accepted view,
21 as you understand it?

22 A Yes.

23 Q. You understand that the predominant
24 source of heroin in the United States is Mexican
25 drug trafficking organizations?

Frye Hearing - Dr. Keyes

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1
2 A I believe Mexico and China are both
3 sources, from what I understand.

4 Q. When it comes to New York, you know that
5 the civil lower cartel in Mexico has been identified
6 as having control over the New York market?

7 A I'm not familiar with the specific
8 cartels.

9 Q. You're aware when it comes to
10 manufacturing heroin that's illegal manufacturers,
11 correct?

12 A Yes.

13 Q. They're the ones who decide how much to
14 manufacture, correct?

15 A I'm not familiar with cartel decision
16 practices.

17 Q. DEA licensed manufacturers of
18 prescription opioid don't manufacture or decide how
19 much to manufacture when it comes to illegal heroin,
20 correct?

21 A I would assume so.

22 Q. When it comes to the amount that's
23 shipped into the New York market, that's something
24 that illegal criminals do, right?

25 A I would imagine.

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1
2 Q. That's not something the DEA licensed
3 distributors of FDA-approved drugs do, correct?

4 A That's correct.

5 Q. And when it comes to deciding how much
6 heroin will be sold, what the price it will be sold
7 at, how pure it will be, that's illegal criminals
8 making those decisions, correct?

9 A I would imagine. I'm not familiar with
10 the decisions of the drug cartels.

11 Q. But those aren't decisions made by
12 manufacturers, DEA licensed manufacturers, DEA
13 licensed distributors, correct?

14 A I would assume not.

15 Q. Pretty shocking if it were true?

16 A It would be.

17 Q. And you've seen no evidence of that?

18 A No.

19 Q. Are you aware starting around 2013 drug
20 cartels started mixing heroin with illegal Fentanyl?

21 A The evidence is consistent with that.

22 Q. And they did that to boost their
23 profits, because Fentanyl is more potent than
24 heroin?

25 A That is the assumption.

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1
2 Q. Specifically, I think you said this in
3 your report, an amount of Fentanyl equivalent to 2
4 grains of salt, can be enough to cause an overdose,
5 right?

6 A That's right.

7 Q. And that has led in turn to an increase
8 in illegal drug overdoses, correct?

9 A Yes.

10 Q. It was illegal criminals that made the
11 decision to pour the Fentanyl into heroin to be
12 sold, correct?

13 A Yes.

14 Q. That decision was not made by any
15 Defendant in this case, correct?

16 A As far as I know, no.

17 Q. Have illegal criminals caused harm from
18 heroin and illegal fentanyl; just yes or no?

19 A Yes.

20 MR. REISMAN: Objection to form. The
21 question is vague.

22 MR. SCHMIDT: I think the witness has
23 proved it's not vague by giving a yes answer.

24 THE COURT: Doctor, you understood the
25 question?

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2 THE WITNESS: Can you repeat the
3 question.

4 THE COURT: Repeat the question.

5 Q. Have illegal criminals caused harm
6 attributable to heroin and illegal Fentanyl; yes or
7 no?

8 THE COURT: That's like would you have
9 those notorious factors that a court should
10 accept.

11 MR. SCHMIDT: I think it's obvious, but
12 I just want to confirm that the witness
13 agrees with it. I think she agrees with it.

14 THE COURT: The bad guys created the big
15 problem, right?

16 THE WITNESS: Bad guys did contribute to
17 the problem, yes.

18 THE COURT: The bad guys being the
19 cartels and street merchants of heroin,
20 correct?

21 THE WITNESS: Yes.

22 THE COURT: Okay. Go ahead.

23 Q. Where I'm going with that is your report
24 doesn't contain any analysis of how different the
25 problem with illegal heroin and illegal Fentanyl

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would be but for these actions by criminal actors;
does it?

A The report suggests there would be less
harm now than if those illegal actors had not been
acting.

Q. Okay. So if they were to reduce price,
increase production, increase purity, increased
other standards, have you quantified, can you tell
us how much less the harm from heroin and Fentanyl
would be than it is today?

A I don't have a specific number.

Q. You don't know if it would be 100
percent lower, 1 percent lower, somewhere in
between, right?

A It's somewhere in between those two.

Q. It would be meaningfully lower though,
correct? Yes or no, if you can answer yes or no.

A It would be lower.

Q. Last thing I'm going to show you, this
is an article you talked about on direct
examination.

Do you remember? It was demonstrative
57. If we can put it up on the screen, an article
by Muhuri. It was on slide 21. And if you need

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another copy I can give you another copy so you don't have to sift through a growing pile of documents.

Do you remember talking about this article on direct examination?

A Yes.

Q. There was a slide talking about this article; is that right?

A That's correct.

Q. What I want to do is show you some data from this article that you did not discuss on direct, specifically can you go with me to page 11 of this document, which is table 3?

A Yes.

Q. Table 3 is looking at people who started using heroin based on different factors they present, correct?

A Just give me a moment to --

Q. Sure.

A -- familiarize myself with this table.

Q. Why don't we pull up ahead, Mr. Reynolds, if we could...

(READING:) Percentage distribution of past year heroin initiates aged 12 to 49, by

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demographic and geographic characteristics and prior illicit drug use status.

A Yes.

Q. And they do it for three different time periods and that it combines time periods of 2002 through 2011; do you see that?

A Yes.

Q. One of the factors these authors -- this is an article you relied on, correct?

A Yes.

Q. And it's an article that you believe follows generally accepted principles?

A Yes.

Q. One of the factors they look at to see how it is related to later heroin use is prior nonmedical prescription opioid use, correct, or opioid misuse, as you call it?

A Yes.

Q. Just if we can look down at the very bottom, I guess it's actually already up on the screen.

Do you see where it says: "Prior nonmedical prescription use and that the aggregate data of 79.5 percent of those people who used heroin

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in this study had previously used nonmedical prescription opioids;" do you see that?

A I'm sorry, is this table 3?

Q. This is table 3, down at the bottom.

Are you looking at table 3 or figure 3?

A I'm looking at table 3 but --

MR. SCHMIDT: May I approach, your

Honor.

THE COURT: Yes.

THE WITNESS: I apologize. Oh, you know what, there's -- the table 3 continues on two pages, and I was looking at the wrong page. I apologize.

MR. SCHMIDT: No, no worries at all.

Q. Are you with me now?

A Now I'm with you.

Q. This report in this study, the 79.5 percent of people who had heroin use had prior nonmedical prescription opioid use; is that correct?

A That's correct.

Q. That same group, though, 79.5 percent had prior illicit drug use, correct? And that's the number on the bottom right corner.

A That's correct.

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1
2 Q. And prior illicit drug use, if you go to
3 the next page where it says footnote 2, is defined
4 as -- if we pull footnote 2 it includes marijuana,
5 hashish, cocaine, including crack, hallucinogens and
6 inhalents; do you see that?

7 A Yes.

8 Q. Just as a more general proposition, do
9 you know what percentage of heroin users who are
10 using heroin today started using marijuana or
11 cocaine or other illegal drugs, other than
12 prescription opioids?

13 A It's a majority.

14 Q. Do you know what percentage -- do you
15 know with anymore particularity than that?

16 A Not off the top of my head.

17 Q. Do you know what percentage of people
18 who have used heroin abused alcohol before using
19 heroin?

20 A Abused alcohol? Do you mean have
21 alcohol use disorder?

22 Q. Or abused it in some way, used it
23 excessively in some way.

24 A It's a majority.

25 Q. Can you quantify more than that?

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A I can't.

Q. Okay. Am I right that your own research has shown that past-year drug use, other than nonmedical use of prescription opioids and alcohol use disorder are the strongest factors associated with nonmedical use prescription opioids?

A Yes.

Q. Is that -- do you stand behind that view?

A Yes.

Q. And is that a generally accepted view in your understanding?

A Yes.

MR. SCHMIDT: That's all I have. Thank you, doctor, appreciate your time. Thank you, your Honor.

THE COURT: Mr. Ercole, are you okay?

MR. ERCOLE: Yes, your Honor.

THE COURT: Just give your name once again, who you represent.

MR. ERCOLE: Sure. Brian Ercole, and I represent the Teva Defendants in this case.

THE COURT: Doctor, you're going to be examined like on the screen. Mr. Ercole is

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someplace else.

THE WITNESS: Right.

THE COURT: He's feeding in, so to speak.

THE WITNESS: Okay.

THE COURT: You may proceed. Go ahead.

MR. ERCOLE: Thank you, your Honor.

EXAMINATION BY

MR. ERCOLE:

Q. Good afternoon, Dr. Keyes. I'm at a slight disadvantage because I can't see you and I'm not sure if you can see me, and I'm sorry.

THE COURT: Let's address that. Mr. Ercole indicates he can't see the witness.

MR. REISMAN: We see her on the screen here. We see both Mr. Ercole and the witness.

MR. ERCOLE: Okay. My screen, for what it's worth, I can see, I have a clear view of your honor, but I don't have a view of the witness, but I mean that's been the case all day, so I'm happy to proceed as planned.

THE COURT: Okay.

MR. ERCOLE: Dr. Keyes, I'd like to

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focus on your marketing causation opinion.

THE WITNESS: Okay.

MR. ERCOLE: Can we pull up Dr. Keyes' report in this case.

Q. And in particular, Dr. Keyes, if you can turn to section 2 of the report, which I believe you have a copy in front of you.

A Yes.

Q. And section 2 of your report, which is on page 6, is -- identifies in section 2 opinions; is that correct?

A That's correct.

Q. It goes on to say: "For the detailed reasons stated in this report, I intend to offer the following opinions in this case:"

Correct?

A Yes.

Q. And in that section you identify 10 opinions, correct?

A Yes.

Q. The word marketing is not mentioned in any of those opinions, correct?

A Correct.

Q. The word promotion is not mentioned in

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any of those opinions, correct?

A Let me just -- that's correct.

Q. No individual Defendant is mentioned in any of those opinions, correct?

A Correct.

Q. Okay. If you can turn to -- is it fair to say that the first time the word marketing appears in your report is on page 13?

A I trust that that is correct.

Q. Appreciate that.

So if we can turn to page 14 of your report, Dr. Keyes, if you can turn to page 14 of your report, more particular, the last sentence -- excuse me -- the second -- the last two sentences of sort of the initial paragraph on that page that starts with "evidence".

A Yes.

Q. And in those sentences you state: "The evidence shows that pharmaceutical marketing of prescription drugs increases prescribers likelihood of prescribing the marketing drug in the future. That is also true for prescription opioids. As a result, increasing marketing of opioid drugs led to increased sales of the marketed drugs."

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Is that correct?

A Yes.

Q. Okay. And those -- those statements there on page 14 of your report are consistent with the opinion that you discussed earlier today with the Plaintiffs' counsel in this case, correct?

A Could you just restate opinion 3, I'm assuming it was the marketing.

Q. Sure. Yes. It was the marketing opinion, and I believe in the PowerPoint you read: "Do you recall that opinion being marketing of prescription opioids increases prescribers likelihood of prescribing opioids in the future?"

A Yes.

Q. Okay. I'd like to get into, discuss with you your qualifications with respect to this particular opinion.

Dr. Keyes, you do not have a degree in marketing, correct?

A I have an undergraduate degree in business, but I don't have any graduate degrees in marketing.

Q. Okay. And you do understand that there's -- there are specific degrees that you can

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obtain in undergraduate for marketing in particular?

A Yes.

Q. Okay. And you don't have one of those degrees, correct?

A That's correct.

Q. And you do not have a Ph.D. in marketing, correct?

A Correct.

Q. You do not teach in the marketing department of any university, correct?

A That's correct.

Q. You have not personally conducted any study on the impact of pharmaceutical marketing, correct?

A That's correct.

Q. And because you have not personally conducted any study on the impact of pharmaceutical marketing, you have not published any study that you could publish without any study that you conducted on the impact of pharmaceutical marketing, correct?

A I have not published any such studies, no.

Q. Okay. And you haven't, you haven't worked for a pharmaceutical manufacturer; have you?

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A No.

Q. And you're not an expert in the business practices of pharmaceutical manufactures, correct?

A That's correct.

Q. And you're not a medical doctor, correct?

A That's correct.

Q. You do not have a medical degree?

A I do not.

Q. You're not licensed to prescribe pharmaceutical medicine?

A No.

Q. And I assume, since you're not licensed, you have not prescribed a pharmaceutical medicine; is that fair?

A That's fair.

Q. And you don't have any formal medical training, correct?

A My training in epidemiology is the formal training I received.

Q. So let me ask it again.

You don't have any formal medical training through a medical school, correct?

A My epidemiology degree is through the

1
2 medical school. I didn't go to medical school to
3 become a physician, but epidemiology is part of
4 medicine.

5 Q. Fair enough.

6 And are you -- you don't have any degree
7 that allows you to assess whether a prescription
8 written by a medical doctor is medically appropriate
9 or inappropriate for a particular patient, correct?

10 A I'm sorry, can you repeat the question?

11 Q. Sure.

12 You don't have any type of medical
13 degree that will allow you to assess whether a
14 particular prescription written by a medical doctor
15 is medically appropriate or inappropriate for a
16 particular patient, correct?

17 A That's within the purview of
18 epidemiology, to assess medication effectiveness.
19 So my training would allow me to make those types of
20 conclusions based on the literature.

21 Q. But you have no medical degree, correct?

22 A I don't have a medical degree, no.

23 Q. Okay. And you're aware that last year
24 Judge Polster in the federal MDL ruled that you were
25 not qualified to opine on the effects the

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Defendants' marketing had on the increased sales and/or increased prescriptions of opioids, correct?

A Yes.

Q. Okay. And if we could pull up the MDL order from Judge Polster at page 2, and if you can pull out the following language.

Dr. Keyes, are you aware that Judge Polster made the finding that "Also as to Keyes, the Court finds that although she is highly qualified as an expert in epidemiology, Plaintiffs have not shown this expertise extends to her opinions on marketing causation in this case."

Are you aware of that finding?

MR. REISMAN: Your Honor, just before the witness answers, I don't have any hard copies of the exhibits that Mr. Ercole is using in court.

MR. HALPERIN: I apologize. I do have them.

MR. REISMAN: If you can hand them out.

THE COURT: What I can do is I will, of course, I have a copy of the decision he's referring to. I can, of course, see, as is my job, to make sure whatever he, whatever

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the examiner recites is, in fact, an exact recitation. However, for purposes of redirect examination, I will see that you have a full copy of the decision.

MR. SCHMIDT: Mr. Ercole, just identify the --

THE COURT: It's Docket 2518, filed August 26th 2019, 14 pages.

MR. REISMAN: Thank you, your Honor.

Q. Dr. Keyes, do you have a copy of that document in front of you now?

A I do.

Q. Okay. Thank you. And I just wanted to ask you a couple of questions on this.

But you're aware of the finding that is highlighted on the screen right now that we just talked about?

A Yes.

Q. Okay. And you're aware of the Court's finding in the next sentence that, that states that: "The Court will exclude the limited portions of their opinion and purport to find causation with respect to the effect that Defendants' marketing efforts had on increased sales and/or increased

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prescriptions of opioids, correct?

A Yes.

Q. Okay. And one of the opinions that we talked about, that you purport to give in this case is the same opinion that you tried to give in the federal opioid MDL proceeding, correct?

A Can you expand on that?

Q. Sure. Sure.

One of the opinions you purport to give in this case is that marketing caused an increase in prescription opioids, correct?

A I do have the opinion that marketing caused an increase in opioid harms and sales.

Q. And that's the same opinions that you purported to give in the federal MDL case that was the subject of this excluding order, correct?

A Yes. My report in this case has differences in that section.

Q. The answer is "yes," though, correct?

A Yes.

Q. Okay. You have not received a medical degree in August of 2019 when Judge Polster issued this opinion; have you?

A No.

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1
2 Q. And you haven't received any type of
3 marketing degree in the last year; have you?

4 A No.

5 Q. You haven't received any additional
6 degrees in the last 12 months, correct?

7 A No.

8 Q. You haven't received any additional
9 marketing related certifications in the last 12
10 months, correct?

11 A Correct.

12 Q. One of the things I believe you
13 testified earlier to that, that you've done since
14 submitting your MDL report, is that you reviewed and
15 analyzed the Hadland studies that are referenced in
16 the slides that you were shown this morning; is that
17 correct?

18 A Those and other studies.

19 Q. But it's your testimony that one of the
20 things you've done since submitting your report in
21 the MDL case, federal MDL case, is reviewing the
22 Hadland studies from -- that were discussed earlier
23 today, correct?

24 A In addition to other studies, that yes
25 to the Hadland studies, and also other studies.

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Q. Fair enough.

And, Dr. Keyes, I'd ask if you can limit your answers to yes or no I would appreciate that.

A I apologize. I will try.

Q. Thank you very much.

Are you aware that those studies were all submitted in connection with your first -- strike that.

Are you aware that those studies, the Hadland studies that were referenced earlier this morning were all cited in connection with your MDL report?

A Yes.

Q. And so your MDL report referenced all of the studies, all of the Hadland studies that were discussed this morning, correct?

A The Hadland studies, yes.

Q. Okay. And so Judge Polster reached his decision that you were not qualified to provide an opinion on marketing causation in the federal MDL, despite your analysis of and reliance on the Hadland studies in your first MDL report, correct?

A Yes.

Q. Let's focus a little bit on the -- let's

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2 move into the methodology for -- that you used here
3 with respect to your marketing causation opinion.

4 I'd like to direct your attention to
5 slide 7 of the slides that you were shown earlier
6 today.

7 Do you have that in front of you, Dr.
8 Keyes?

9 A Is that titled methodology?

10 Q. It is, and it should be up on the screen
11 right now.

12 A Then, yes, I have it.

13 Q. I apologize for talking over you if I
14 do. As I indicated, I can't see you directly, so
15 I'm trying to do my best.

16 This slide, slide 7 is titled
17 Methodology, correct?

18 A Yes.

19 Q. Okay. And this is the methodology you
20 used in this particular case, correct?

21 A It is among the methodologies yes.

22 Q. Well, there's no mention of marketing in
23 this slide; is there?

24 A No.

25 Q. There's no mention of promotion here?

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A There's not.

Q. No mention of any of the manufacturer Defendants marketing in this slide type of methodology?

A No.

Q. Your methodology in this case with respect to your marketing causation opinion did not involve reviewing any specific marketing materials of any manufacturer Defendant, correct?

A That's correct.

Q. Your methodology did not involve the review of any specific marketing communication attributable to any manufacturer Defendant in New York, correct?

A I'm sorry, can you repeat the question?

Q. Sure.

Your methodology did not involve the review of any specific marketing communications attributable to any manufacturer Defendant in New York, correct?

A I believe those are in the open payment database that was used in the Hadland study.

Q. We'll address -- we'll get into that. And then let me, let me sort of emphasize my

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question. Let me rephrase my question.

You did not look at any specific marketing communications of any manufacturer, correct?

A Can you just define what you mean by a "marketing communication"?

Q. Fair enough.

So you didn't look at any specific marketing statements attributable to any manufacturer Defendant in New York, correct?

A A marketing statement outside the ones that are included in the open payments database or --

Q. Well, let me ask you this:

Are any manufacturer statements actually included in the open payment data base?

A I guess I'm -- if you can just describe what you mean by a statement. I'm not trying to be obstructive. I'm just -- I included what was in the open payments database. If something was not in the open payments database, it was not included in my analysis.

Q. The open payment database does not include any content of any specific interactions

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2 between any manufacturer sales representative in any
3 position, correct?

4 A I believe you're correct, yes.

5 Q. Okay. And it doesn't include the
6 content of any specific interactions whatsoever
7 between manufacturers and physicians, correct?

8 A I don't believe so.

9 Q. Meaning, yes, correct, for that
10 statement?

11	A	Yes.
----	---	------

12 Q. So your methodology did not involve, in
13 this case, did not involve the review of the content
14 of any specific interactions between manufacturer
15 Defendants and physicians in New York, correct?

16	A	Correct.
----	---	----------

17 Q. And it didn't involve the review of any
18 specific statements as opposed to, for instance,
19 payment of attributable to any manufacturer
20 Defendant in New York, correct?

21 A That's right.

22 Q. And as far as your methodology in this
23 case, you're not familiar with what opioids, if any,
24 these manufacturer Defendants in this case actually
25 marketed in New York, correct?

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A I'm sorry, say that again. The --

Q. Sure.

As part of your methodology in this case you're not familiar with what opioids, if any, each manufacturer defendant actually marketed in New York, correct?

A That's correct.

Q. Part of your -- excuse me -- as part of your methodology in this case, you have not evaluated when any manufacturer Defendants, if it did at all, marketed any opioid product in New York, correct?

A I mean, to the extent that that was in the open payments database, that information would be available. I think in one of the Hadland studies they do break down by state, and so we can look at what the Hadland study has for New York State for that particular question.

Q. So why don't we -- do you recall giving a deposition in this case, doctor?

A Yes.

Q. Can you turn to -- I assume you have a copy of your deposition transcript in front of you?

A I do.

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Q. Okay. And can we turn to page 384 of your deposition transcript.

A Yes.

Q. Can you turn to line number -- excuse me -- if you turn to 384, question on line 17. The question is:

"As you sit here today, you don't know what time period Mallinckrodt marketed opioid products in New York?

ANSWER: That's correct.

QUESTION: Is your answer the same for Allergan?"

"Yes."

"QUESTION: Janssen?"

"I think my answer is going to be the same for all of them."

Do you recall giving that testimony?

A Yes.

Q. So sitting here today you can't identify when a manufacturer Defendant ever marketed any opioid products in New York, correct?

A I think we can look at the Hadland study. It might shed some light on that, I'm not sure. But we can open that study up to see if there

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2 | was relevant time periods.

3 Q. Other than the Hadland study, to the
4 extent it has or does not have any of those time
5 periods in there, your methodology didn't evaluate
6 reviewing when particular manufacturers promoted
7 particular products in New York, correct?

8	A	That's correct.
---	---	-----------------

9 Q. And as part of your methodology in this
10 case you have not done anything to determine how
11 many manufacturers of opioids there are, correct?

12	A	That's correct.
----	---	-----------------

13 Q. And you have not determined how many
14 manufacturers of opioids marketed or opioid medicine
15 was marketed in New York between 1996 and the
16 present, correct?

17	A	How many total companies?
----	---	---------------------------

18	Q. Yes.
----	---------

19 A I think that would be in the open
20 payments database.

21 Q. Sitting here today -- I apologize for
22 talking over you.

23 A I could look in the Hadland study and
24 see if that information is available. Off the top
25 of my head I don't know.

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1 Q. And that's not included in your report,
2 correct?
3

4 A That's correct.

5 Q. Sitting here today you don't know
6 whether the Hadland study does or does not include
7 the number of manufacturers of opioids that marketed
8 the medicine in New York between 1996 and the
9 present, correct?

10 A Right.

11 Q. Given that you have not reviewed any of
12 the Defendants' marketing materials in this case,
13 you have not analyzed the specific impact of those
14 marketing materials, correct?

15 A Of which marketing materials?

16 Q. Let me repeat my question.
17 Given that you have not reviewed any of
18 the Defendants' marketing materials in this case,
19 you have not analyzed the impact of any of those
20 specific marketing materials, correct?

21 A Incorrect.

22 Q. You haven't reviewed any of the
23 Defendants' marketing materials, right, that's been
24 established?

25 A That's correct.

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1 Q. Okay. Do you understand there's a
2 difference between truthful marketing and false or
3 misleading marketing?
4

5 A I'm generally aware that there would be
6 truth and falsehood in marketing, yes.

7 Q. So meaning some statements may be true
8 and some statements may not be true, correct?

9 A I would imagine so, yes.

10 Q. And you are not giving in this case any
11 opinion on whether any particular manufacturer
12 Defendants' marketing materials are false or
13 misleading, correct?

14 A No, I am giving that opinion. There is
15 other literature that talks about materials
16 underestimating the risk of addiction.

17 Q. You do not know, Dr. Keyes, whether any
18 of those materials were used by any of the
19 manufacturer Defendants in this case, correct?

20 A That's correct.

21 Q. You do not know what, if anything, any
22 manufacturer Defendants may have said about any of
23 those materials, correct?

24 A Say that again. I'm sorry, I'm just --
25 it's hard to on Zoom or Team to take it in.

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Q. Fair enough.

You mentioned that there are -- you mentioned studies that talked about downplaying the risk of opioid use in marketing materials, correct?

A Yes.

Q. Okay. And we established that -- strike that.

With respect to those studies, you don't know whether any manufacturer Defendant in this case ever cited or used any of those citings in connection with any interactions with New York physicians, correct?

A Correct.

Q. Okay. And you don't know what, if anything, any manufacturer Defendant might have said about those studies with any New York physician, correct?

A Sorry, give me -- you're asking me if I know what manufacturer said to physicians?

Q. I'm asking you, in connection with the studies we're talking about, you don't know what, if anything, any manufacturer Defendant might have said about those studies in New York, correct?

A I know what the literature says about

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1 the materials, but I am not aware of specific
2 conversations, for example.

3
4 Q. Let me repeat my question. And, again,
5 I ask you to try to keep this to a correct or
6 incorrect, or a yes or no, if you can.

7 A Okay. I apologize.

8 Q. With respect to the studies that are --
9 that we've been talking about, that you say some
10 marketing materials may have downplayed the risk of
11 those studies, you do not know what any manufacturer
12 Defendant may or may not have said about any of
13 those studies in New York, correct?

14 A Correct.

15 Q. And that's because you didn't review any
16 of those marketing materials, right?

17 A No.

18 Q. Okay. You didn't review any of those
19 marketing materials, though, right?

20 A I did not review specific marketing
21 materials.

22 Q. Okay. And you're not giving an opinion
23 on what percentage, if any, of any manufacturer
24 Defendants' marketing materials are supposedly false
25 or misleading, correct?

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A A specific percentage?

THE COURT: You're not testifying as to truth or voracity of the marketing materials?

A That's correct.

THE COURT: Next question -- time out.

Excuse me, I said truth or voracity, it's the same thing, truth or untruth.

Q. Dr. Keyes, your methodology did not evaluate whether any New York prescriber received any false or misleading marketing statement from any manufacturer Defendants in this case, correct?

A That's right.

Q. And you agree that there are many factors, other than marketing, that may influence a particular prescriber to write an opioid prescription, correct?

A Yes.

Q. Okay. And your methodology did not evaluate whether any New York prescriber was influenced by any false or misleading statement from any manufacturer Defendant to write an opioid prescription as opposed to those other factors, correct?

A Can you say the question again?

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Q. Sure.

Your methodology did not evaluate whether any New York prescriber was influenced by any false or misleading statement from any manufacturer Defendant in this case to write an opioid prescription as opposed to the many other factors that had influenced prescribing, correct?

A I would say that's incorrect.

Q. And can you identify for me any New York prescriber who was influenced by any false or misleading statement from any manufacturer Defendant in this case?

A Not a particular prescriber, no.

Q. And your report doesn't identify any such prescribers, correct?

A I don't identify prescribers, no.

Q. And your report conducted no statistical analysis of -- strike that.

Your methodology in this particular case did not evaluate whether any New York prescriber -- strike that.

Is there any section in your report that you can point us to that would indicate which statements, if any, from any of the manufacturer

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Defendants in this case actually influenced New York prescribers to write opioid prescriptions?

A You're asking about specific statements from specific Defendants in this case, no, that's not, that's not in the report.

Q. Right. And so your report does not identify whether any New York prescribers were actually influenced by specific statements from particular manufacturer Defendants in this case, correct?

A No, I would say that part of the -- there's a leap from the question before to this question that I think is covered in the literature, and I'm happy to expand on that, if you'd like me to.

Q. Well, let's ask this.

None of the literature that you reference in your report addressed the specific marketing materials of these Defendants in this case, correct?

A Correct.

Q. And that's what I'm asking about. Sort of focus on my question a little bit.

I'm asking you about with respect to the

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1 statements of these manufacturer Defendants in this
2 case, you cannot identify for me anywhere in your
3 report where any of those -- where you identify any
4 situation where those statements influence a New
5 York prescriber to write an opioid prescription,
6 correct?
7

8 A I think that's generally correct.

9 Q. You talked earlier today about
10 questionnaires that certain authors have used in
11 connection with publishing studies; do you recall
12 sort of talking about that earlier today?

13 A Yes.

14 Q. And you talked earlier today about
15 surveys that some epidemiologists have used in
16 connection with studies; do you recall that?

17 A Yes.

18 Q. As part of the methodology of your
19 causation opinions here, you have not conducted any
20 independent study or survey of New York prescribers,
21 correct?

22 A That's correct.

23 Q. And you haven't done any type of -- you
24 haven't sent out any systematic questionnaires to
25 New York prescribers to understand why they write

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prescriptions, correct?

A That's correct.

Q. So as a result, you have not conducted any study or surveys of New York prescribers to determine whether they received any specific marketing statements from the Defendants in this case, correct?

A That's right. I have not done such a study.

Q. And you haven't done any cite or survey to understand why it is that New York prescribers write opioid prescriptions, correct?

A I believe that's available in the literature, so I would say that's incorrect.

Q. Please, Dr. Keyes, let me rephrase my question, because I think it was more basic than that, which is: You have not conducted any study or survey of New York prescribers to understand why they write -- I'll rephrase it.

You have not conducted any study or survey of New York prescribers to determine whether they wrote an opioid prescription because of any marketing statement from any Defendant, correct?

A That's correct.

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1
2 Q. And you didn't conduct any study or
3 survey or even send out any questionnaires of New
4 York prescribers to determine what it is they
5 actually understood about opioids when they wrote
6 opioid prescriptions, correct?

7 A Can you say that question again?

8 Q. Sure.

9 You have not conducted any study or
10 survey or sent out any opioid questionnaires in
11 connection with your opinion in this case to New
12 York prescribers to determine what they understood
13 when they wrote an opioid prescription, right?

14 A I have not done such a study.

15 Q. And as part of your methodology in this
16 case, you didn't evaluate the conduct of any
17 particular manufacturer Defendant, correct?

18 A I believe some particular manufacturers
19 are identified in some of these publications and
20 that is the extent to which these manufacturers have
21 been identified in the report.

22 Q. You don't identify any of the
23 manufacturer Defendants by name in your report,
24 correct?

25 A That's correct.

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1 Q. And apart from looking at studies, apart
2 from looking at studies, you didn't evaluate the
3 conduct of any particular manufacturer Defendant in
4 this case, correct?

5 A I relied on the literature, yes.

6 Q. In this particular case you're not
7 planning to offer an opinion about the marketing
8 conduct of any particular manufacturer Defendant in
9 New York, correct?

10 A That's correct.

11 Q. Let me take an example, if you don't
12 mind, just to try to sort of tease out this
13 methodology.

14 Have you ever heard the name Watson
15 Laboratories, Inc.?

16 A It sounds familiar, but I don't have
17 expertise in that particular company.

18 Q. Do you know whether that company is a
19 Defendant in this case?

20 A I haven't heard that name.

21 Q. Did you evaluate what medicine that
22 company makes?

23 A No.

24 Q. Did you evaluate whether that company
25

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1 makes and sells any opioid medicine?

2 A I have not evaluated that.

3 Q. Did you evaluate whether that company
4 actually promotes any of those opioid medicines in
5 New York?
6

7 A I have not evaluated that.

8 Q. Did you evaluate when they promoted, if
9 they did at all, any of those medicines?

10 A No.

11 Q. Did you evaluate how they were promoted?

12 A No.

13 THE COURT: Mr. Ercole, with all due --
14 great deal of respect, if she never heard of
15 the company, what good are the questions?

16 MR. ERCOLE: I would respectfully
17 submit, your Honor -- but let me ask this,
18 I'll tie this up now...

19 Q. Dr. Keyes, would it surprise you to
20 learn that that is a Defendant in this particular
21 case?

22 A Would it surprise me -- I'm sorry, say
23 that again.

24 Q. Would it surprise you to learn that that
25 company is a Defendant in this particular case?

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A It would not surprise me.

Q. And it wouldn't surprise you because that was not part of your methodology, correct?

A That's correct.

Q. And just so I understand, and that answer would apply to each of the specific Defendants, manufacturer Defendants in this case, correct?

A Some have been more prominent than others in literature, so some I'm familiar with -- many I'm familiar with, especially if they've been repeatedly cited in the literature I'm more familiar with the companies.

Q. Well, let's see if we can summarize a little bit here.

Your methodology in this particular case did not evaluate whether any of the manufacturers, who are Defendants in this case, actually made marketing statements about opioids in New York, correct?

A The -- correct.

Q. And it did not evaluate what specific opioid medicine they marketed, corrected?

A Some literature does cover that, so I

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would say that's incorrect.

Q. Sitting here today -- well, you certainly haven't evaluated all of the opioid medicine that each of the manufacturer Defendants in this case market, correct?

A That's right.

Q. And you did not evaluate when each of those opioid products was marketed in New York, correct?

MR. REISMAN: Objection.

Asked and answered.

THE COURT: Sustained.

Q. Dr. Keyes, you have not conducted your own statistical analysis to determine how many -- excuse me. Strike that.

Doctor Keyes, you have not conducted your own statistical analysis to determine how many opioid restrictions, if any, were influenced by the marketing of any manufacturer Defendant in this case as opposed to other factors, correct?

A Correct.

Q. And you have not conducted your own statistical analysis to determine how many opioid prescriptions, if any, were influenced by any false

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or misleading marketing of any manufacturer
Defendant, correct?

MR. REISMAN: Objection.

Asked and answered.

THE COURT: Answer it again.

A I believe that that is in the
literature, so I believe that that's included in my
report.

Q. Dr. Keyes, let me re-ask that question.

You have not conducted your own
statistical analysis to determine how many opioid
prescriptions, if any, were influenced by any false
or misleading marketing of any manufacturer as
opposed to other factors, correct?

A I relied on the literature, so it is
correct that I did not do my own study, I relied on
published studies.

Q. None of those studies, Dr. Keyes,
evaluated specific statements by specific
manufacturer Defendants in this case, correct?

A There's no specific statements, no.

Q. So when you say you relied upon the
literature, that literature does not actually
identify any false or misleading or other marketing

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statements by any of the other manufacturing Defendants in this case?

A I believe there is discussion of misleading statements in some of these articles, and they're attributed to various companies.

THE COURT: The question is: Are the statements connected to a Defendant in this case?

THE WITNESS: I believe there is some literature on some specific Defendants in this case that we could look at in some of the citations.

Q. Sitting here today -- we'll get into some of those studies -- sitting here right now, can you identify a specific study that evaluated a specific statement by any of the manufacturer Defendants in this case?

A No.

Q. In fact, if we could pull up your deposition transcript at page 381. If we can go to line 9. If you pull up line 4 is where it begins.

"QUESTION: Do now who the manufacturing Defendants are in this case currently?"

And you state: "I know it's a bit of a

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1 moving target, but I try to keep up a little bit,
2 but I know some of them."

3 "Okay. Which ones can you name right
4 now?"

5 "ANSWER: And I was going to prepare for
6 this, so it's Teva, J&J, Janssen, Endo, Allergan,
7 and those are the ones I can name off the top of my
8 head. There may be others.

9 QUESTION: As you sit here today, can
10 you point to me any study that evaluated the
11 marketing material of those specific companies?
12

13 ANSWER: No."

14 Do you see that?

15 A Yes.

16 Q. And that was accurate at the time you
17 gave that testimony, correct?

18 A Correct.

19 Q. And it remains accurate today?

20 A Yes.

21 Q. And if you continue down in your
22 deposition there's a question that's presented and
23 then you give another answer, and if I can point you
24 to page 382, line 6 through 11, you state:

25 "But the specific marketing materials of

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any specific company, except for the Purdue one that I mentioned, I have not seen an extensive epidemiological report on those companies' specific marketing materials."

Is that correct?

A That's correct.

Q. That was true at the time you gave that testimony?

A Yes.

Q. That's true today, correct?

A That's correct.

Q. The link back to the questions that I was asking, you have not conducted your own statistical analysis to determine whether any marketing by any manufacturer Defendant in this case actually caused any medically and inappropriate opioid prescription in New York, correct?

A I can infer from the literature on that, but whether there's a specific marketing statement I'm not aware of a study that's listed that.

Q. And you haven't done your own statistical analysis, correct?

A That's correct.

Q. And that's because you relied upon

1 literature, correct?

2 A That's correct.

3 Q. You talked this morning about harms
4 associated with opioids in New York; do you recall
5 that testimony?
6

7 A Yes.

8 Q. That some of those harms included
9 overdose; do you recall that?

10 A Yes.

11 Q. Your methodology in this case does not
12 trace any of those harms to an opioid prescription
13 written because of any particular marketing
14 statement by any particular manufacturer Defendant
15 in this case, correct?

16 A Again, I think when you look at the
17 literature as a whole one can draw that conclusion,
18 but if there's -- there's no specific prescription
19 that I've evaluated.

20 Q. There's no particular marketing
21 statement that you evaluated, correct?

22 A That's right.

23 Q. Okay. And so let me just rephrase this
24 question so we can get an actual, you know, sort of
25 correct or incorrect.

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Your methodology in this case does not trace any of the harms associated with opioids, that you discussed earlier today, to an opioid prescription written because of any particular marketing statement by any particular manufacturer Defendant in this case, correct?

A Incorrect. I mean, the methodology is actually what does the tracing. That's exactly what the methodology does, actually.

Q. Your report did not identify any opioid prescription written because of any particular marketing statement by any particular manufacturer Defendant in this case, correct?

A Wait, say that again.

Q. Your report does not identify any specific opioid prescription written because of any particular marketing statement by any particular manufacturer Defendant in this case, correct?

A No specific prescription, that's correct.

Q. And because you haven't identified any specific prescription in your report, your report does not identify any of the harmed, low income subject prescription, correct?

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1 A So from any one prescription, no, but it
2
3 looks at the bulk of prescriptions.

4 Q. But it doesn't identify any of the
5 specific prescriptions that would have been
6 influenced by any specific marketing statements by
7 any manufacturer Defendant, correct?

8 A No one prescription, no. It draws
9 inference from associations.

10 Q. In fact, it doesn't identify any
11 specific prescriptions in New York, correct?

12 A That's right. I'm sorry, I guess I --
13 can I qualify that answer or --

14 THE COURT: Go ahead.

15 THE WITNESS: -- or restate it?

16 A We do look at prescriptions in New York.
17 I mean, my report does include data on prescriptions
18 in New York.

19 THE COURT: The question suggests a
20 particular prescription.

21 THE WITNESS: Right. No one particular
22 prescription.

23 THE COURT: And carrying it through the
24 chain, and the answer is no?

25 THE WITNESS: Right. That's right.

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Q. The opinion that you are giving on marketing causation is based upon studies that other academics have done, correct?

A That's right.

Q. And would you agree that the epidemiological literature shows that whether a pharmaceutical industry interactions and influence prescribers depends on both the product and type of marketing that is done?

A Can you say that again?

Q. Sure.

Does the epidemiological literature that you relied upon, does that show that whether pharmaceutical industry interaction can influence prescribers depends on a product and type of marketing that is done?

A I believe that's generally what the literature states.

Q. And you testified to that effect during your deposition, correct?

A Yes.

Q. And would you agree that the academic literature, when it comes to the impact, if any -- strike that.

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1 Would you agree that the academic
2
3 literature contains studies for particular products
4 that do not show an effective influence of marketing
5 on sales?

6 A There have been -- yes. There are
7 studies where marketing has not influenced sales.

8 Q. And you would describe the academic
9 literature on the impact of marketing on prescribing
10 as kinergies (phonetic), correct?

11 A Yes.

12 Q. In this particular case -- and let me
13 just make clear that I fully understand your
14 testimony -- so you would agree that there are two
15 factors that can influence whether or not -- strike
16 that.

17 You agree that with respect to the
18 evidence in the epidemiological literature that it
19 hinges upon, A, the product, and B, the type of
20 marketing at issue, right?

21 A Among other factors.

22 Q. And in this particular case, you would
23 agree with me that there are many -- strike that.

24 You would agree with me that there are
25 many different types of opioid medicines, right?

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A Yes.

Q. I think we've discussed this, but you don't know what particular type of opioid medicine that each manufacturer Defendant in this case marketed, correct?

A No.

THE COURT: "No," not correct, or "yes," that is correct.

THE WITNESS: Yes, that is correct.

Q. And you don't know all of the specific types of marketing conduct or statements, if any, that the manufacturer Defendants in this case engaged in with respect to New York, correct?

A I know some of them but not all of them.

Q. You know some of them because of the open payment database; is that correct?

A That's right.

Q. And again, that open payment database that you're referring to, does not include the content of any specific marketing statement or communication with any physician, right?

A That's right.

Q. I'd like to -- we've been referencing -- strike that.

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Earlier today there were slides that addressed the Hadland articles; do you recall that?

A Yes.

Q. Okay. And there were three Hadland studies; do you recall that?

A Yes.

Q. And with respect to those Hadland studies, none of those Hadland studies evaluated the impact, if any, that any particular marketing statements by any particular manufacturer Defendant in this case had on opioid prescribing, correct?

A Right. That's correct.

Q. None of those studies even looked at any particular marketing statements, correct?

A That's correct. Those three studies, no.

Q. None of those studies evaluated whether statements by pharmaceutical sales representatives about the risks and efficacy of opioid medicine had any impact on opioid prescribing, correct?

A Can you repeat the question?

Q. Sure.

None of the Hadland studies that you referenced earlier today evaluated whether

statements by pharmaceutical sales representatives about the risks and efficacy of opioid medicines had any impact on opioid prescribing, correct?

A Incorrect.

Q. None of those studies, Dr. Keyes, evaluated statements by sales representatives about the risk and efficacy of opioid medicines, correct?

A Specific statements were not included in the article.

Q. Right. And they weren't studied by those authors in that article, correct?

A To the extent that marketers made statements about the risks and benefits of opioid prescribing, those would be included in the marketing. No specific statements were included, but if statements were made about the risks and benefits, that would be included in the marketing that was done. So I would include that in the study material.

Q. And you're using the word "if," correct?

A Yes.

Q. Let me rephrase that question.

You don't know whether or not any of the -- any of the -- any of the data collected by

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1
2 the authors of those articles actually evaluated
3 particular statements regarding the safety and
4 efficacy of opioid medicines, right?

5 A They did not evaluate specific
6 statements.

7 Q. Okay. So with respect to specific
8 statements, those studies didn't draw any particular
9 conclusions regarding those statements, right?

10 A That's correct.

11 Q. And those studies certainly didn't
12 distinguish between marketing statements that are
13 truthful and marketing statements that are not
14 truthful, correct?

15 A That's right.

16 Q. And they didn't isolate the impact, if
17 any, of any false marketing statements as opposed to
18 a truthful marketing statement on opioid
19 prescribing, correct?

20 A Correct.

21 Q. None of those Hadland studies reached
22 any conclusion about causation as opposed to
23 association, correct?

24 A Each study in and of itself did not.

25 Q. So I'd like to actually turn to --

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before I do so, let me ask you this:

In connection with the presentation, the slide presentation that was made earlier today, the Hadland articles were the only articles referenced regarding the impact of marketing on prescribing behavior, correct?

A Incorrect -- oh, I'm sorry, can you repeat the question?

Q. Sure.

In connection with the slide presentation that was given today, the only articles referenced there regarding the impact of marketing on opioid prescribing are the Hadland articles?

A I apologize, I did not understand the question. That was correct.

Q. Those authors looked at data on payments made to physicians and reported to CMS under the Sunshine Act, correct?

A Yes.

Q. If we can turn to I believe it's Demo Exhibit 50. Do you have that document in front of you, Dr. Keyes?

A I do.

Q. This is the first Hadland article from

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September of 2017, correct?

A That's right.

Q. And if you turn to the conclusion -- excuse me -- if you look at page 1493, and there's a section that references conclusions; do you see that?

A Yes.

Q. And you were shown that statement earlier today, correct?

A Yes.

Q. And that statement doesn't reach -- there is no specific causation conclusion or finding associated with this article, right?

A That's right.

Q. And there's no even association finding associated with this article, correct?

A No -- I mean, you are -- sorry, you are incorrect.

Q. Okay.

MR. REISMAN: Your Honor, I'm sorry to interrupt Mr. Ercole, I just want to note the time and object to the continued examination, if there will not be time left for redirect.

THE COURT: Well, I've been thinking

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about that. Despite the budgetary issues the court system is facing, I would like to finish the doctor today, and I'll ask my Clerk to contact the administrative offices and ask for overtime.

As a matter of fact, I may have even said that in one of our conferences, that in the event we were running short on time on a witness and had other engagements or difficulty coming again, I would ask for overtime.

Is everybody okay with that?

Doctor, how are you?

THE WITNESS: That's fine.

THE COURT: They're going to ask me how much time, tell them about an hour.

MR. REISMAN: Thank you, your Honor.

And just to give a guideline, I will try to keep redirect as brief as possible, ten minutes or so.

THE COURT: That's good to know. That means they will give me more time than I needed.

Mr. Ercole, how much more do you have to

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go?

As I recall, and I do recall specifically this particular -- these sentences were presented to the witness, and the Court itself asked to go back to it and know that these findings should prompt an examination of industry influences on opioid prescribing.

Mr. Ercole, again, I'm not cutting anybody short, don't get that impression. How much time are you going to need to complete your cross-examination?

THE WITNESS: No longer than 15 minutes, your Honor.

THE COURT: Say that again.

MR. ERCOLE: No longer than 15 minutes.

THE COURT: The morning session somebody told me ten minutes, then it went to 45 minutes.

MR. REISMAN: I accept the blame for that. I would also just note that we have, at least on the letter that Defendant submitted, another potential questioner, Mr. Herman, and I don't know if he's going to --

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THE COURT: Oh, yeah. I forgot.

Mr. Herman, are you with us? Because I haven't seen his picture up there.

Does anybody know, does Mr. Herman intend to --

MR. HERMAN: Your Honor, I'm here. I'll put my picture up. There's a green screen they put behind me, I thought that would be a little distractive, but I'm here.

THE COURT: Did anybody catch that?

THE WITNESS: He's here.

THE COURT: Mr. Herman, do you intend to examine?

MR. HERMAN: Your Honor, at this point I do not.

THE COURT: Okay. Let's take 15 minutes, because it's been a lengthy session. We'll come back.

(WHEREUPON, a short recess was taken.)

THE COURT OFFICER: Come to order.

THE CLERK: Part 48 is back in session. Doctor, I remind you you're still under oath.

THE WITNESS: Thank you.

THE CLERK: Please be seated.

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THE COURT: Everybody on board?

Please be seated. Thank you.

You may continue.

Mr. Ercole, can you hear me?

MR. ERCOLE: Yes, I can, your Honor.

Thank you.

THE COURT: Okay.

CONTINUED EXAMINATION BY

MR. ERCOLE:

Q. Dr. Keyes, we looked at the first
Hadland studies from 2017 before we broke, correct?

A Yes.

Q. That study, again, was limited to open
payment data regarding nonresearch payments to
physicians, correct?

A Correct.

Q. Okay. If you turn -- if we could pull
up Demonstrative 49, which was shown to you earlier
today, and if you can turn to that document, Dr.
Keyes, it would be -- we'll call it the second
Hadland study from 2018.

A Yes.

Q. Do you see that?

A I do.

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Q. And that's titled Association of
Pharmaceutical Industry Marketing of Opioid Products
to Physicians with Subsequent Opioid Prescribing,
correct?

A That's correct.

Q. So the title references association not
causation, right?

A That's right.

Q. And you looking -- (VIDEO CUT OFF)

A I'm sorry, you cut off for a minute.

Can you just repeat the question?

Q. Sure. Absolutely.

The second -- the first sentence of the
second paragraph reads: "Pharmaceutical industry
marketing to physicians is widespread, but it is
unclear whether marketing of opioids influences
prescribing;" do you see that?

A Yes, I do.

Q. Okay. And so these, with respect to the
authors of this study as of 2018, their opinion was
that it's unclear whether marketing of opioids
influences prescribing, correct?

A I think it had not been quantified.
There had been other material written about that,

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1 but that's what these authors write in terms of the
2 quantification had not been available until the open
3 payment database was released.
4

5 Q. Well, this actually says: "It's unclear
6 whether marketing of opioids influenced
7 prescribing," correct?

8 A That's what is written.

9 Q. Okay. And, again, the open payment
10 database that was studied here did not contain any
11 information about statements made by manufacturers
12 about opioids, correct?

13 A It did not contain statements, that's
14 correct.

15 Q. So as a result -- and as a result, the
16 study didn't evaluate those particular statements,
17 right?

18 A It did not evaluate particular
19 statements, no.

20 Q. Well, we don't know whether it evaluated
21 any statements whatsoever, right?

22 A I believe that in terms of the types of
23 marketing efforts that were included in the open
24 payments database are listed in the result section,
25 some of which would involve talking.

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1
2 Q. Correct. But we do not know what the
3 content of any of those communications, correct?

4 A That's correct.

5 Q. Statements like -- and for all we know,
6 when looking at sort of payments, for instance,
7 associated with, with meals to physicians, that
8 could involve a situation where a sales rep just
9 drops off a lunch with a particular doctor without
10 ever saying anything, correct?

11 A I, I suppose. I don't know. I can't
12 evaluate that statement.

13 Q. Well, we can't evaluate that statement
14 because we just don't know -- because the open
15 payments data does not contain anything associated
16 with the consents of any interactions between
17 manufacturers and physicians, correct?

18 A The content of the statements is not
19 included, but the contents of the marketing is.

20 Q. Well, let me see if I can rephrase this.
21 Would you agree that the type of
22 marketing is contained, but not the content of any
23 of that marketing, correct?

24 A The statements that are said during the
25 marketing encounter are not included.

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Q. If you turn to the -- turn to the second to last paragraph of this particular study on page 863.

A Yes.

Q. This paragraph reads: "Limitations include the possibility of reverse causality, because physicians who receive industry payment may be predisposed to prescribe opioids. Our findings establish an association, not cause and effect."

Correct?

A That's correct.

Q. So at least the authors of this opinion -- of this study were saying our findings do not and cannot establish causation, correct?

A That's not what they said.

Q. Okay. There's a third, a third Hadland article that was referenced earlier today and that is from 2019.

Do you recall the discussion of that particular article?

A Yes.

Q. If you turn to, I believe it's Demonstrative 51.

A Yes.

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1 Q. That's titled Association of
2 Pharmaceutical Industry Marketing of Opioid Products
3 With Mortality From Opioid Related Overdoses; is
4 that correct?
5

6 A Yes.

7 Q. And, again, the title refers to
8 association, not causation, right?

9 A That's right.

10 Q. And, once again, in this particular
11 study what was being used as a source for marketing
12 information was the overpayments database, correct?

13 A Yes.

14 Q. And that -- and the study, by using that
15 open payments database, looked at transfers or
16 payments -- strike that.

17 As part of that open payments database
18 the study looked at transfers of value from a
19 pharmaceutical company to a physician for
20 nonresearch, right?

21 A That's right.

22 Q. And this particular study also does not
23 purport to find causation between any nonresearch
24 payments and physician prescribing, correct?

25 A That's right.

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Q. And the authors of this, this study from 2019 also recognized the number of limitations, correct?

A They did.

Q. And if you turn to the last page of this particular document labeled "limitations;" do you see that?

A Yes.

Q. Page, I believe it's 9 of 12.

And the first limitation that they identify is that: "Our findings demonstrate associations between opioid marketed and subsequent prescribing and mortality from overdoses. We cannot exclude reverse causation."

Correct?

A That's what's written.

Q. And another limitation they identify in this particular study is that they were not able to distinguish between appropriate opioid prescribing from potentially inappropriate prescribing, correct?

A I'm sorry, where is that written? I just want to make sure I know what they said.

Q. Sure. Fair enough.

If you look down to the fourth -- I

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1 think it's the second to last sentence of that
2 particular document.
3

4 A Yes. That is what is written.

5 Q. And that's because by looking at the
6 data they had, couldn't determine whether or not
7 payments, nonresearch related payments to physicians
8 actually influenced inappropriate opioid
9 prescribing, correct?

10 A I'm sorry, say -- the question is
11 whether they could determine whether payments were
12 associated with inappropriate prescribing?

13 Q. Yes.

14 A They looked at overall prescribing, not
15 the appropriateness of the prescribing, so that's
16 correct.

17 Q. And with respect to this study, they
18 also recognized one of the limitations that we've
19 been talking about, which is that the overpayments
20 database does not include further information on the
21 nature of industry physician interactions, correct?

22 A That's right.

23 Q. And that limitation is what we've talked
24 -- strike that.

25 And it goes on to say: "It is possible

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1
2 that some industry payments to physicians resulted
3 in a crude knowledge around safer prescribing
4 practices; do you see that?

5 A Yes.

6 Q. And so as a result of this study, is it
7 fair that the author concluded that they were not
8 able to determine whether or not payments actually
9 improved knowledge around safe prescribing practices
10 for opioids as opposed to having a detrimental
11 impact on safety prescribing practices?

12 A That was not an outcome that was
13 evaluated in the study. We don't have information
14 on that.

15 Q. And you have not done any separate
16 evaluation to make such a determination, correct?

17 A That's correct.

18 Q. The authors of this particular study ran
19 a regression analysis, correct?

20 A Let me just -- yes, they did.

21 Q. Okay. And you have not done any type of
22 independent regression analysis in this particular
23 case, correct?

24 A Can you clarify what you mean by that?
25 Have I done a regression --

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THE COURT: Analysis.

Q. Right. I'll rephrase the question.

In connection with your marketing causation opinion in this particular case, you have not run any regression analysis, correct?

A In specific to marketing causation, no, I did not.

Q. And because you haven't done that, you haven't been able -- you haven't done any type of statistical or other analysis to isolate the impact of any particular statement by manufacturers in this case, correct?

A Well, the authors of the study did control for a number of economic and other related factors, but maybe I'm not understanding the question.

Q. Sure. I'm asking you -- well, we looked at what the authors did and didn't do in this particular study, right?

A Yes.

Q. Okay. And one of the things they didn't do in this study was analyze any particular statements, marketing statements, right?

A That's correct.

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1 Q. Okay. And you, in this particular case,
2 have not done any, in connection with your marketing
3 causation opinion, have not done any statistical
4 analysis to isolate the impact of any false or
5 misleading marketing statements by any of the
6 manufacturer Defendants here, correct?
7

8 A Correct.

9 Q. And with respect to the Hadland studies
10 that we looked at and that were referenced in your
11 presentation in a PowerPoint earlier today, we've
12 talked about how they didn't reach a causation
13 conclusion, right?

14 A These -- I'm sorry, can you repeat the
15 question?

16 Q. Yeah.

17 The studies that we've been referencing,
18 the Hadland studies that we just walked through,
19 none of those studies separately reached a causation
20 opinion, right?

21 A Separately they did not.

22 Q. Okay. And you are the only one, is that
23 correct, in this particular case, using those
24 studies that are reaching a causation conclusion,
25 correct?

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1
2 A I don't believe I'm the only one. In
3 epidemiology I think it's a well-accepted
4 conclusion.

5 Q. Well, you are reaching a causation
6 conclusion based upon the Hadland articles that they
7 did not reach, correct?

8 A I am looking at the totality of the
9 evidence. So I agree with the authors for each
10 study. I think they went -- they had the correct
11 conclusion, but when you look at the literature
12 overall I think you can draw a more -- a broader
13 conclusion.

14 Q. And just to summarize, just a couple of
15 questions before I conclude.

16 The literature that we've been -- that
17 you've been referring to -- strike that.

18 None of the articles in the literature
19 that we've been referring to draw a causation
20 conclusion regarding the impact of marketing on
21 prescribing, correct?

22 A Are you speaking of the three Hadland
23 articles?

24 Q. I'm speaking of the three Hadland
25 articles.

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Correct?

A Correct. Each study alone does not draw a causal conclusion.

Q. Right. And we talked -- and none of the studies that you've cited or relied upon in your report actually address the impact of any marketing statements or materials by any of the manufacturer Defendants in this case, correct?

A That's correct.

MR. ERCOLE: Those all the questions I have, your Honor.

THE COURT: Okay. Thank you.

Mr. Herman.

MR. HERMAN: Your Honor, no questions at this time.

THE COURT: Okay. Redirect.

Mr. Herman, you say "at this time..."

MR. HERMAN: Your Honor, I have no questions for the witness. Thank you.

REDIRECT EXAMINATION

MR. REISMAN:

Q. Dr. Keyes, I will try to be as brief as possible on redirect here. I just would like to go over a few topics that were addressed during

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cross-examination.

First, Mr. Schmidt asked you some questions about the Bradford Hill factors; do you recall that?

A I do.

Q. Would you say as an epidemiologist that it is necessary for each and everyone of the nine Bradford Hill factors to be met in a situation before you can draw a causal inference?

A No.

Q. Are the Bradford Hill factors exhaustive?

A No.

Q. In the epidemiological literature, do researchers use those nine factors as a checklist when they write and publish articles?

A No.

Q. When you have written and published articles in the field, have you used the Bradford Hill factors as a checklist?

A No.

Q. Mr. Schmidt also suggested that you have not, in fact, discussed anything relating to the Bradford Hill factors in your report, and he pointed

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to your methodology section.

Let me ask you this question: In your report did you discuss material and studies in the context of addressing factors that are included in the Bradford Hill factors?

A Yes.

MR. REISMAN: Dan, if you can please put up P23954 and turn to page 14. This is your expert report, Dr. Keyes.

And if you could scroll to the bottom of the page, heading B, and enlarge that, please.

THE WITNESS: Which page is it?

MR. REISMAN: It's page 14.

Q. So, you know, we could go through a number of examples of this, but I just want to point this one out to the Court.

So this is from your report, heading subsection B, it says: "Risks of opioid use disorder following medical use of prescription opioids follow a dose response pattern."

Did I read that correctly?

A Yes.

Q. So is this an example of your use in the

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body of your report of one of the Bradford Hill factors?

A Yes, it is.

Q. I actually want to talk about the next -- the first sentence under B, it says: "Early studies cited in marketing materials to physicians underestimated the addiction potential of prescription opioids and concluded claims that risks of opioid use disorders are rare among those prescribed opioids."

Did I read that correctly?

A You did.

Q. Now, Mr. Ercole asked you a number of questions about whether you reviewed marketing materials of the Defendants and whether the studies that you reviewed regarding marketing themselves analyzed the marketing materials of the manufacturers.

Let me ask you this question: As a hypothetical, if the Defendants had provided information, including marketing materials, to physicians that underestimated the risks of opioid use disorders, do you believe, as an epidemiologist, that that would have had an impact or an influence

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on the prescribing of opioids?

A Yes.

Q. Now, while we're on this page, I also want to address a document that Mr. Schmidt showed you from the New York State Department of Health, it was a flier from approximately 2007, 2008; do you recall that?

A I do.

Q. With respect to the Defendants, and this is another hypothetical, if it were the case that the Defendants have provided information to governmental agencies, including the New York State Department of Health, that underestimated the risks of opioid use disorder, do you believe that that information would have influenced the publication of flyers, such as the one Mr. Schmidt showed you?

MR. SCHMIDT: Objection.

MR. ERCOLE: Your Honor, I'd like to object to this. I think it's an improper hypothetical and I think it's -- it's certainly beyond the scope of her report.

MR. SCHMIDT: And I'll further object as vague in terms of which Defendants he's talking about.

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THE COURT: You tailed off. You further say what?

MR. SCHMIDT: Vague in terms of which Defendants he's talking about.

THE COURT: Okay. Rephrase the question.

Q. We'll focus on the manufacturers.

So as a hypothetical, Dr. Keyes, if it were the case that the manufacturer Defendants in this case --

THE COURT: Reframe the hypothetical. You may ask the witness to assume certain facts.

MR. REISMAN: Okay. Thank you.

Q. Assume that the manufacturer Defendants in this case provided information to the New York State Department of Health that underestimated the risks of addiction from prescription opioids, would that information have had an influence on the publication of flyers, documents like the one Mr. Schmidt showed you?

A I don't --

THE COURT: Time out. First of all, do you know or you don't know the answer to

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that?

THE WITNESS: I know the answer to that.

THE COURT: Now there's an objection. I assume it's the same objection.

MR. ERCOLE: From --

THE COURT: Excuse me. The law in New York is quite clear. If, in fact, the predicate for a hypothetical question is not established in the record, the answer is of no moment, okay.

Now given that, what's your objection?

MR. ERCOLE: Your Honor, it's an improper hypothetical and beyond the scope of the opinions that are included in her report, so I just want to preserve that for the record.

THE COURT: Okay. Answer the question.

A I don't think I need to make an assumption. I think that there is evidence that the -- that there was -- there were statements that underestimated the risk of addiction, not only to government officials, but to medical schools, to a whole wide variety of industries that then put out material and textbooks and educational materials

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that misstated the risks of addiction, so I do think that under that assumption that there would be an increase in prescribing.

Q. Did any of those materials that you just described perceive -- were they -- withdrawn.

To your knowledge, were any of those materials that you've just described issued before 2008?

THE COURT: Issued before when?

MR. ERCOLE: Again, your Honor, objection.

THE COURT: Time out. Time out.

MR. REISMAN: I'm asking about the materials --

THE COURT: You said issued before what? You tailed off.

MR. REISMAN: 2008.

THE COURT: Just yes or no.

MR. ERCOLE: Your Honor, if I can just log my -- for the record, again, no foundation and beyond the scope of her report.

THE COURT: Okay. Beyond the scope and no foundation. I don't get the foundation

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part.

MR. ERCOLE: Sure, your Honor. I believe he's referencing, if I understood the question, certain materials that have not been, have not been produced, certainly that I have not seen, and, you know, it's also based upon the assumption of manufacturers somehow influencing all of these sources, so I again --

THE COURT: And, by the way, unless that assumption that the lawyer is asking the witness to assume is not established in the record, that's the Reilly case in New York, Reilly versus one of the hospitals in Port Jefferson, it is of no moment. All right. Mr. Reisman, be advised.

MR. REISMAN: Thank you, sir. Thank you, your Honor.

Q. So I'll ask the question again.

To your knowledge, did the materials that you've described a minute ago, were they issued before 2008?

A To my knowledge, yes.

Q. Let's turn, if we can, to 17.

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THE COURT: Bradley versus St. Charles
Hospital.

Q. Page 17 of your report. And I just
briefly want to focus on, if we can turn to page 17,
which is the exhibit we're looking at, towards the
bottom of the page, in the middle there's a sentence
that begins with the name Portenoy.

A Yes.

Q. So do you see that? And let's bring
that up on the screen and enlarge it.

So in your report, the sentence we're
looking at describes a study that was authored by
Portenoy and others that was published in 2007; is
that correct?

A That's correct.

Q. That was an industry sponsored study; is
that right?

A Yes.

THE COURT: Which industry sponsored it?
You said it was an industry-sponsored study,
what industry?

THE WITNESS: I would have to look at
the study.

THE COURT: All right.

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THE WITNESS: I mean, pharmaceutical,
the pharmaceutical industry, the drug
leaders, manufacturers.

THE COURT: Do you know that?

THE WITNESS: I know that it was drug
manufacturers, but I'm not certain of which
one.

THE COURT: Okay.

Q. Now, there were questions from both Mr.
Schmidt and Mr. Ercole regarding the limitations
sections of some of the studies that you cited in
your report; do you recall that?

A Yes.

Q. In peer-reviewed scientific journals is
it required that researchers include limitations
sections in their studies in order for those studies
to be published?

A Typically in journals they require a
transparent limitation section.

Q. So there's nothing unusual, is there,
about limitations being included in a study; is
there?

A No.

Q. I want to turn to the question of the

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causal relationship that you have opined on between the use of prescription opioids and subsequent OUD and heroin and fentanyl abuse.

During your testimony today have you discussed a study that focused on the link between medical use of opioids and heroin use?

A Have I focused on any particular study that looked at that?

Q. Have we discussed any particular study on that subject?

A I don't think we have. We've looked at not -- we've looked at studies that have looked at nonmedical and medical use.

Q. Did the Lankenau study that you discussed today address medical use?

A Yes.

Q. What did it say about medical use of opioids?

A That it often precedes nonmedical use.

Q. Did that study specifically have a finding on medical use of opioids?

A Yes.

THE COURT: I hate to interrupt you, going back to an objection I heard five

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minutes ago, you asked a question about 2000 -- going back to 2007, and see if I have this right, I believe you put a question to the doctor that based upon the -- we'll call it the comments or statements of the, I believe the FDA, right, whether or not that had a connection to the marketing activities of the Defendants; was that about it?

MR. REISMAN: I'm not sure that was it. I was referring to marketing statements by the manufacturer Defendants.

THE COURT: Which came from where?

MR. REISMAN: It came from the manufacturers themselves.

THE COURT: What spawned, in your line, what spawned these marketing statements in or about 2007?

MR. REISMAN: Well, they were in materials, and they were in studies that were sponsored by the manufacturers.

THE COURT: And what allowed -- what was the license, let's say, for the Defendant manufacturers to issue those statements?

MR. REISMAN: Well, I don't think they

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needed a license to make those statements.

THE COURT: I'm asking about license in the legal sense. There were applications before the Food and Drug Administration, correct?

MR. REISMAN: Yes.

THE COURT: And based upon those results, those findings, the approvals of the Food and Drug Administration, the manufacturers, some of the Defendants issued -- well, they didn't issue, they marketed, correct?

MR. REISMAN: Correct.

THE COURT: Right. Are you asking the witness -- and if I got it wrong you'll tell me -- are you asking the witness to speculate on the, on the link between FDA and marketing as to causation?

MR. REISMAN: Well, I'm not asking about the FDA, I'm asking about the manufacturer Defendants' own activities and the impact on the last DOH and on prescribers.

THE COURT: To the extent any witness speculates, the Court will discount it so --

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MR. ERCOLE: Your Honor -- I'm sorry to interrupt.

MR. REISMAN: Yeah, I just want to finish. So I was trying to address the point that Mr. Schmidt raised earlier today regarding that flier that he showed Dr. Keyes that she hadn't seen before.

THE COURT: Mr. Ercole, do you have something to say?

MR. ERCOLE: Yeah. Only that we're talking about hypothetical statements of manufacturers that the witness has already stated under oath that she never reviewed or looked at, so I just want to make that objection clear.

MR. SCHMIDT: Just to further that on his point about speculation, the statement that was just made now that the witness hadn't seen that document, how could she possibly know what influenced it or what the origin of it was? There's been no discovery, that I'm aware of, that's been produced on that. Nothing on her list.

THE COURT: In any event, it's not a

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Perry Mason moment. Let's move on.

Q. Okay. Just a few more questions, Dr. Keyes.

I just want to -- I'm not going to go through each of the studies that Mr. Schmidt, respectfully, cherry picked statements out of, but I just want to focus on one of them, which is the Compton study. It's DEFNY05561.

MR. SCHMIDT: Object to the lawyer commentary. I don't think it's appropriate.

THE COURT: Say again.

MR. SCHMIDT: Object to the lawyer commentary, I don't think it's appropriate, your Honor.

THE COURT: All right. Ask questions.

Q. So --

THE COURT: Time out. You all can tell the witness what you're going to direct them to, that's not -- just don't editorialize or opine.

Q. So, Dr. Keyes, we'll put up -- you have the exhibit in front of you, and, Dan, if you can bring up that exhibit and please show page 157 on the left side under the graph. Just a few more

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pages in, and if you can highlight the sentence that begins with the words: These studies over the current trends heading.

So this is the Compton study; is that right?

A That's right.

Q. Did you rely on this study in your report?

A Yes, I did.

Q. I'll read that sentence: "These studies suggest a clear link between nonmedical use of prescription opioids and heroin use, especially among persons with frequent nonmedical use or those with prescription opioid abuse or dependence."

Did I read that correctly?

A You did.

Q. Is that sentence summarizing the authors' review on a number of studies?

A Yes.

Q. For my last topic today I just want to go back to the marketing causation piece, and Justice Garguilo I believe this morning had a question about some of the authors or one of the authors of one of the Hadland studies.

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And, Dan, if you can bring up Demo 51, page 10, and if you can highlight the section towards the top that says: Author Affiliations.

So, Dr. Keyes, in looking at the author affiliations of the authors of this particular Hadland study, which is the 2019 study, can you describe briefly to the Court what the qualifications for those individuals are?

A I can describe their affiliations.

Q. Can you describe, are they epidemiologists?

A I just know that several of them have degrees in epidemiology and some of them have affiliations in Department of Epidemiology, as well as Department of Health.

Q. So in that listing of their affiliations and the departments they work in, are any of those individuals, any of the authors of this study listed as marketing professors?

A No.

Q. So do you have a view as to whether it is necessary to be an expert in marketing to conduct epidemiological research and form opinions about marketing causation?

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1
2 A I believe that epidemiologists can form
3 those opinions without a degree in marketing.

4 Q. I just want to go to one more section of
5 this document. If we turn back to page 8, please.

6 Can you please highlight the paragraph
7 that begins with the words: Pharmaceutical
8 Industry, the third paragraph under discussion.
9 This sentence reads: "The pharmaceutical industry
10 invests tens of millions of dollars annually in
11 direct to physician marketing of opioids, and it is
12 improbable that companies would provide payments to
13 physicians if such marketing did not either increase
14 prescribing rates or maintain high levels of opioid
15 prescribing; did I read that correctly?

16 A You did.

17 Q. Is that statement consistent with your
18 opinions on marketing causation in this case?

19 A They are.

20 Q. Now, in forming your opinions on
21 marketing causation in this case, have you taken
22 into account the limitations that Hadland and
23 coauthors mentioned in their studies?

24 A I did. I have.

25 Q. And have they changed your opinions in

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any way?

A No. I think that the way these studies were conducted was rigorous. In addition to regressions there were numerous statistical controls, and when you look at the evidence altogether, I think it is a very clear picture for which causal inference can be drawn.

Q. So taking into account those limitations, you are still able, as an epidemiologist, to draw a causal inference from this body of literature?

A Yes.

Q. I just have one more question for you, Dr. Keyes, and we're not going to show the document. Justice Garguilo has it, I think everyone else does. This is the Judge Polster's decision in the MDL, and page 20, I'd like to just read the sentence to you.

At the bottom it says: "In other words, Keyes has not shown that she applied epidemiological methods to determine that a cause effect relationship may be inferred from the study that she cites." And it's referring to one particular study.

Can you explain to the Court today how you applied epidemiological methods to determine

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that there is a cause effect relationship between the marketing of prescription opioids and the prescribing of prescription opioids?

A Yes. I looked at these epidemiological studies and I evaluated those responses. I evaluated the strengths of the association. I looked to see whether they ruled out alternative causes. I looked at analogy, consistency, plausibility and other factors and determined that they do meet those benchmarks that are common in the epidemiological literature.

Q. And based on that you were able to form your opinion about the cause and effect relationship; is that right?

A That's right.

MR. REISMAN: Thank you, your Honor.

THE COURT: Thank you.

Doctor, just one question.

THE WITNESS: Yes.

THE COURT: Actually, it's two.

You submitted a report in connection with the Ohio case?

THE WITNESS: I did.

THE COURT: And did you recite Bradford

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Hill criteria in the Ohio case?

THE WITNESS: I didn't use Bradford Hill criteria specifically, but I used the same principles.

THE COURT: Yeah, but did you actually recite Bradford Hill criteria?

The only reason why I ask, gentlemen, is that Judge Polster spent a couple of pages on the application of Bradford Hill criteria.

THE WITNESS: No, I didn't.

THE COURT: That's the only reason I ask.

Thank you very much, doctor, you're excused.

A couple of things. Tomorrow we'll commence at 9:45, I intend to continue until about 1:30, and then I think I told everybody yesterday we have a ceremony here tomorrow, which I will attend, a 911 ceremony at 3 p.m. Leaving -- breaking at 1:30 will give the staff an appropriate luncheon recess.

There's something else. I would like you all to take back -- when I say "all," not only the people here, the people that are

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1 participating through the live stream -- when
2 we're done with the Frye hearings the Court
3 intends to lift its stay on motion practice.
4 The stay on motion practice occurred, as I
5 told you at a prior conference when we were
6 notified about 51 new applications -- new
7 motions. Most of those motions are motions
8 in limine. I think 4 of the 51 or 52 were
9 subject to that nature.
10

11 The Court has reviewed every single
12 motion in limine, has made some notes and has
13 consulted with some of the Special Masters.

14 I am suggesting to all of you that the
15 mass majority of your petitions, your motions
16 in limine, deal with some very basic tenets
17 of evidence.

18 I would like you to meet and confer
19 among yourselves to work out the -- call
20 it -- we'll call it a Stipulation or an
21 Agreement as to those motions.

22 I mean, there is some very basic stuff,
23 stuff in there about hearsay. I'm drawing a
24 blank, but it's most of them are things, are
25 things, objections that can be raised at

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trial, and the Court would rule from the bench. They're not difficult. Please do that, because I would like to abbreviate that process and no overinvolve the Court or the Special Masters.

Tomorrow we have Mr. -- Dr. Tomarken, correct?

MR. REISMAN: Yes, your Honor.

THE COURT: Just thinking ahead, I do have this courtroom also for Monday.

Do you suspect, given the abbreviated day tomorrow, I'm going to have to continue to Monday with Dr. Tomarken?

And I realize he's a Suffolk County resident, right?

MR. SHERIDAN: Tom Sheridan from Suffolk County. Yes, Judge, he is a Suffolk County resident, and my direct examination I think will be completed in about an hour-and-a-half.

THE COURT: Okay. So safe home everybody. Thank you for your presentation, I appreciate it.

MR. SCHMIDT: Your Honor, may I raise

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one question that I've been asked to raise on behalf of all the Defendants.

Your Honor had allowed us to file a brief at the close, a week after the close of the last witness, and there's two requests we wanted to make on it. One is the date is moving around because of when the witnesses will finish. Originally it was September 22nd.

The first request is can we have until September 25th, a few extra days; and the second is can we have, instead of the 50 pages your Honor ordered, 60 pages; so 10 pages per witness, or 20 pages for Defendant group?

THE COURT: You want 60? You can have the extra time.

MR. SCHMIDT: Thank you, your Honor.

THE COURT: Just keep in mind the Court's focus on these hearings. The Court has set forth its focus in writing in connection with the issues presented at a -- I call it a Frye hearing, but I think all of you know that Frye has been evolving rapidly

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in New York, that's why we nicknamed it "Fryebert". So the answer is yes, you can have the extra time.

MR. SHERIDAN: Your Honor --

THE COURT: Yes.

MR. SHERIDAN: Regarding the reschedule for Dr. Tomarken, I very much would like to complete him in one day. So if there's any question that we can't complete him tomorrow, I don't want to have to come back again on Monday. If your Honor wishes, we can simply do it on Monday and do a full day on Monday. So I'm offering that for your consideration.

In any event, I'd like to be able to start him and complete him in one day so he doesn't have to come back.

MR. SCHMIDT: Your Honor, I'm not the one examining. I'm not the one. Miss Flahive Wu is on the phone, I think it's going to be about two hours for at least the distributor examination.

THE COURT: Look, I'm good either way. I have this room for Monday, too, correct?

THE CLERK: Yes.

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MR. SCHMIDT: I don't think we would object. Just proactive putting it on Monday, just doing it in one day.

MR. REISMAN: I propose Monday. I would like to be able to complete it Monday.

THE COURT: I think we all could use a breather tomorrow. 9:45 Monday.

Thank you gentleman and ladies.

MR. SCHMIDT: Thank you.

MR. SHERIDAN: Thank you.

THE COURT: Doctor, thank you for coming in.

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